

**UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS**

JOHN HANCOCK LIFE INSURANCE)	
COMPANY, JOHN HANCOCK)	
VARIABLE LIFE INSURANCE)	
COMPANY, and MANULIFE)	
INSURANCE COMPANY (f/k/a)	
INVESTORS PARTNER LIFE)	
INSURANCE COMPANY),)	CIVIL ACTION NO. 05-11150-DPW
)	
Plaintiffs,)	
)	
v.)	
)	
ABBOTT LABORATORIES,)	
)	
Defendant.)	
)	

PLAINTIFFS' TRIAL MEMORANDUM

Introduction

Plaintiffs John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Manulife Insurance Company (collectively “John Hancock” or “Hancock”) respectfully submit this trial memorandum in support of their claims against defendant Abbott Laboratories (“Abbott”) in accordance with Section II.6 of the Court’s Second Amended Order Regulating Non-Jury Trial, dated January 15, 2008. Hancock commenced this action in June 2005 because it had reason to believe that Abbott had violated the parties’ March 2001 “Research Funding Agreement” (the “Agreement”) by, *inter alia*, misrepresenting the actual condition of, and prospects for, certain “Program Compounds” encompassed by that Agreement

in order to induce Hancock to give Abbott millions of dollars to purportedly support the development of those compounds and others.

Time and the discovery process have borne out Hancock's concerns. The available evidence, obtained primarily from Abbott's own documents and witnesses, establishes that, at a minimum, Abbott misrepresented or failed to disclose material, adverse information about at least three of the Program Compounds (*i.e.*, ABT-518, ABT-594 and ABT-773) that almost certainly would have caused Hancock (or any other reasonable investor) to decline to enter into the present Agreement, or even to enter into any contract with Abbott at all. Material, adverse information that Abbott *admits* it misrepresented or failed to disclose to Hancock in the Agreement includes, without limitation:

- Rather than considering ABT-518 to be a “compelling development candidate” as Abbott expressly represented to Hancock in the Agreement, Abbott actually *halted* the development of ABT-518 the week before the Agreement was signed due to concerns over the “low prospects of success” for that compound. Plaintiffs’ Preliminary Proposed Findings of Fact and Conclusions of Law (“HFOF” or “HCOL”), ¶¶ 68(c); 72(c)-(e). Abbott only partially recommenced the development of ABT-518 on the day that the Agreement was signed (*i.e.*, March 13, 2001) after Dr. Jeffrey Leiden, the Executive Vice President of Abbott’s Pharmaceuticals Division, was reminded by others within Abbott that ABT-518 was part of the planned Hancock portfolio. *Id.*, ¶ 72(f)-(g). Abbott terminated ABT-518 again, once and for all, shortly after the Agreement was signed. *Id.*, ¶ 75;
- Rather than expecting ABT-594 “to be the first neuronal nicotinic receptor agonist to receive an indication [*i.e.*, regulatory approval] for pain” on which Abbott planned to spend \$“35.0” million in 2001 as it represented to Hancock in the Agreement, Abbott actually had (a) “prematurely discontinued” its only ongoing clinical trial of that compound over two months earlier due to enrollment and drop-out problems resulting from the large number of “adverse events” among trial subjects involving nausea, vomiting and dizziness; (b) simultaneously delayed further clinical trials of ABT-594 and cut its planned spending on that compound in 2001 by more than seventy-three percent (73%); and (c) commenced discussions with other pharmaceutical companies about the possibility of co-developing the compound. *Id.*, ¶¶ 95(e), 98(h), 98(o), 98(l); and

- Rather than believing that ABT-773 had a “likely profile” that was “competitive” with existing antibiotics in terms of “[c]onvenience, safety, tolerability” as Abbott represented to Hancock in the Agreement, Abbott understood in early 2001 that ABT-773 faced “Key Issues” involving serious potential cardiac and liver side effects, dosing uncertainties and pediatric formulation problems that ultimately led Abbott’s senior management to recommend, less than nine months after the Agreement was signed, that Abbott cease further development of that compound. *Id.*, ¶¶ 109(c), 115(a)-(f).

The foregoing are just some of the misrepresentations or omissions that Abbott *admits*, as demonstrated by its own documents, the sworn testimony of its own witnesses, and its own Proposed Additional and Substitute Findings of Facts and Conclusions of Law (“AFOF” or “ACOL”). These admissions alone are sufficient to establish Abbott’s liability to Hancock for breaching the Agreement. If necessary, Hancock also will prove at trial that Abbott’s misrepresentations and omissions were even more extensive and serious than Abbott admits. Timelines that provide a more graphic illustration of the substance and timing of, and evidentiary support for, various misrepresentations and omissions by Abbott with respect to each of the Program Compounds at issue are attached to this Trial Memorandum at Tab 1 (ABT-518), Tab 2 (ABT-594), and Tab 3 (ABT-773).

Hancock also intends to prove that Abbott did not commit the material misrepresentations and omissions that have come to light in this action through mere oversight. The Agreement between Hancock and Abbott took almost a full year to negotiate. When Hancock learned while negotiations still were underway in late 2000 that one compound (ABT-980) in the proposed “basket” of Program Compounds had failed, the loss of just that single compound almost killed the entire deal. HFOF, ¶ 34. Abbott was not about to run the same risk again. As the condition of, and Abbott’s plans for, certain other Program Compounds -- specifically ABT-518, ABT-594 and ABT-773 -- materially changed and declined in the months leading up to the execution of the

Agreement, Abbott said nothing to Hancock for fear that disclosing the changes would be, in Abbott's own words, the "deathnell (*sic*)" of the deal. *Id.*, ¶ 84. Abbott decided, instead, to go forward with the deal and take Hancock's money with the hope that Hancock never would learn of Abbott's deception.

Nor is this a case in which the Abbott personnel who were responsible for negotiating the Agreement with Hancock were simply unaware of the true condition of, and Abbott's plans for, the various Program Compounds encompassed by that Agreement. To the contrary, Dr. Jeffrey Leiden, the Abbott executive who signed the Agreement and represented to Hancock that ABT-518 was a "compelling development candidate" on March 13, 2001, is the *very same* Abbott executive who had ordered an immediate "[h]alt" to "all further expenditure[s]" on ABT-518 due to his concern about the low prospects of success for that compound *less than one week earlier*. HFOF, ¶¶ 50, 72(c); Nabulsi Depo., 145:15-146:9; PLs' FH. Dr. John Leonard, the Abbott executive who purportedly reviewed all of the deal documents for accuracy the day before the Agreement was signed, is the *very same* Abbott executive who urged Dr. Leiden on or about the *same day* to restart the Phase I trial of ABT-518 because that compound was part of the planned Hancock portfolio, and who, by his own admission, was aware that Abbott's Phase IIb trial of ABT-594 had been prematurely discontinued in January 2001 at well less than its original target of 320 subjects. HFOF, ¶ 72(f); Leonard Depo., 55:7-55:14, 166:7-167:17, 168:19-169:3, 170:12-170:17. The only reasonable conclusion to be reached, based on all of the evidence, is that Abbott's senior management *knowingly* and *intentionally* misled Hancock regarding the condition of, and prospects for, ABT-518, ABT-594 and ABT-773 in the Agreement.

Abbott has breached the Agreement and/or defrauded Hancock in other ways as well. First, evidence obtained by Hancock through discovery in this action confirms that Abbott routinely inflated the planned spending numbers that it provided to Hancock in its various Annual Research Plans by providing Hancock not with its intended and *reasonably expected* spending numbers as specifically required under Section 3.4(iv) of the Agreement, but rather with its much higher, non-risk adjusted *nominal* spending numbers. HFOF, ¶¶ 133, 134. Abbott's misrepresentations violated the express terms of the Agreement and caused Hancock to make at least one Program Payment of \$54,000,000 that was not required. *Id.*, ¶ 136.

Second, Abbott has failed to pay Hancock one-third of the unspent "Aggregate Carryover Amount" in violation of the express terms of Section 3.3(b) of the Agreement. *Id.*, ¶¶ 143, 152-153. Abbott has refused to make that payment to Hancock notwithstanding the fact that Abbott's own internal documents acknowledge that Abbott personnel considered any such payment to be simply a partial "refund" of Program Payments that Hancock had made, not an unenforceable "penalty" as Abbott now contends.

Third, Abbott breached its obligations under Section 2.5 of the Agreement by intentionally hindering, delaying and obstructing Hancock's efforts in 2004-2005 to audit Abbott's compliance with the terms of the Agreement as expressly permitted by that provision. *Id.*, ¶¶ 155-164. Abbott aggressively resisted Hancock's attempted compliance audit, and withheld or redacted important information that only came to light in the course of discovery in this litigation, in a further effort to conceal its original misrepresentations, omissions and fraud from Hancock, and to discourage Hancock from pursuing its rights against Abbott.

Lastly, Abbott has breached its obligation under Section 4.3(d) of the Agreement to "maximize the commercial value" of ABT-518 and ABT-594 "to both parties" by failing or

refusing to out-license or divest those Program Compounds to a third party after Abbott had substantially ceased developing those compounds on its own. HFOF, ¶¶ 167-176. As demonstrated by Abbott's own documents, Abbott's management affirmatively has *blocked* any out-licensing of ABT-594 for Abbott's own business purposes (and to Hancock's financial detriment) because Abbott currently has another, replacement NNR compound (ABT-894) in development, and Abbott "would not want [a] competing program" involving ABT-594 undertaken by another pharmaceutical company "with [the] potential for diversion" that it might cause in the marketplace. *Id.*, ¶ 176; PLs' KD.

Abbott's obligations to Hancock under the Agreement -- including, *inter alia*, Abbott's obligation to provide Hancock with complete and accurate descriptions of the various Program Compounds -- are plain and unambiguous. The evidence establishes that Abbott repeatedly has violated those obligations, oftentimes intentionally. As a result of Abbott's contractual violations and intentional fraud, Hancock is entitled to judgment in its favor on Counts I-III of its Second Amended Supplemental Complaint and damages at law or, in the alternative, rescission of the Agreement in its entirety.

Specific Claims and Issues

I. ABBOTT HAS BREACHED THE AGREEMENT AND COMMITTED FRAUD.

Count I of Hancock's Complaint asserts that Abbott has committed fraud. Under Illinois law, to prove fraud and, therefore, entitle Hancock to damages constituting the "difference between the actual value of the property sold and the value the property would have had if the representations were true" (the "benefit of the bargain"). HCOL, ¶¶ 3, 7. Hancock must demonstrate that: (a) Abbott knowingly made a false statement and/or omission of material fact; (b) Hancock relied on that statement and/or omission; (c) Abbott made the statement and/or

omission with the intent to induce Hancock to enter the Agreement; and (d) the statement and/or omission caused harm to Hancock. HCOL, ¶ 4.

The evidence satisfies all of these elements. Abbott's own documents and witnesses provide clear and convincing evidence that Abbott was well aware that the Agreement contained false statements and omitted material facts concerning the condition of, and prospects for, ABT-518, ABT-594 and ABT-773, and that Abbott made those statements and omitted those facts for the purpose of inducing Hancock to go forward with the Agreement. HFOF, ¶¶ 8-130; HCOL, ¶ 9. In most instances, the mere substance of the misrepresented or omitted facts is sufficient to demonstrate their materiality. Abbott's assertions to the contrary simply are not credible. Abbott's further assertions that (1) after demanding that Abbott represent and warrant the condition of, and prospects for, the Program Compounds in the Agreement, Hancock did not actually rely upon those representations and warranties, and (2) given that none of the Program Compounds at issue has yet to generate *any* royalty or milestone payments, that Hancock has not suffered harm on account of Abbott's misrepresentations and omissions, are equally incredible. The overwhelming evidence, as discussed below, supports Hancock's allegations of fraud.

Count II of Hancock's Complaint asserts that Abbott also has breached the Agreement in various ways. In order to prove breach of contract by a preponderance of the evidence, Hancock must demonstrate: (1) the existence of a valid and enforceable contract; (2) the performance of that contract by Hancock; (3) breach of the contract by Abbott; and (4) resulting injury to Hancock. HCOL, ¶¶ 19, 28.

Once again, the evidence can satisfy all of these elements. Abbott does not deny the validity of the Agreement, or that Hancock has made the Program Payments that it was required to make thereunder. Moreover, Abbott's corresponding obligations to Hancock under the

Agreement, as well as its various violations of those obligations and Hancock's resulting harm, are easily demonstrated as discussed below.

A. *Abbott Defrauded John Hancock And Breached The Agreement By Misrepresenting Or Omitting Material Facts Concerning The Program Compounds.*

The terms and conditions of Abbott's representations and warranties under Article 12 are broad and unambiguous. Specifically, Abbott represented and warranted to Hancock in Section 12.2(i) that,

[n]either this Agreement nor any Exhibit to this Agreement (including the compound reports attached as Exhibit 12.2(i) hereto (the "Compound Reports")) contains any untrue statement of material fact or omits to state any material fact necessary to make the statements contained herein or therein not misleading. There is no fact known to Abbott (other than generally available information concerning the pharmaceutical industry in general) as of the date of this Agreement that has not been disclosed in this Agreement or any Exhibit to this Agreement which has resulted in, *or could reasonably be expected to result in*, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial [viability]) of the Research Program or any of the Program Compounds. HFOF, ¶ 60 (emphasis added).

Abbott further expressly represented and warranted to Hancock in Section 12.2(m) of the Agreement that,

[w]ith respect to each Program Compound, since the date of its respective Compound Report, to the knowledge of Abbott, no condition, circumstance or fact has arisen (other than generally available information concerning the pharmaceutical industry in general) nor has Abbott made any change in the conduct of the Research Program which, individually or in the aggregate, has resulted in, *or could reasonably be expect[ed] to result in*, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial [viability]) of such Program Compounds. HFOF, ¶ 61 (emphasis added).

The foregoing representations impose upon Abbott the affirmative obligation to ensure that all material information provided to Hancock in the Descriptive Memoranda and its First Annual Research Plan ("ARP") was accurate and truthful as of the date the Agreement was

signed. HFOF, ¶¶ 60-61. They also impose upon Abbott the affirmative obligation to advise Hancock of any *additional* information known to Abbott that “individually or in the aggregate, has resulted in, or could reasonably be expect[ed] to result in, a material adverse effect on the prospects or condition (including safety, efficacy, scientific viability or commercial [viability])” of any of the Program Compounds as of the date the Agreement was signed. *Id.* Abbott voluntarily undertook these affirmative obligations for the purpose of persuading Hancock to enter into the Agreement (*see* Agreement, Ex. 32 at p. 2 [“NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and undertakings contained herein, the parties hereto agree as follows....”]), and Abbott purported to comply with them at the time by, among other things, explicitly assuring Hancock in writing shortly before the Agreement was executed that Dr. John Leonard, Abbott’s Vice President of Development, had “looked at all of the documents one last time in preparation for execution” and noted only one “oversight”; a slight delay in the commencement of Abbott’s Phase I study of ABT-518.¹ HFOF, ¶¶ 54-57; PLs’ R. By Abbott’s own admission, no other changes, concerns, discrepancies or “oversights” were disclosed to Hancock by Abbott before the Agreement was signed. *Id.*; AFOF, ¶¶ 55-57.

The great weight of the evidence establishes that the Agreement contains various affirmative misrepresentations by Abbott concerning the status, prospects and plans for ABT-518, ABT-594 and ABT-773, and fails to disclose numerous other facts known to Abbott that reasonably could have been expected to have a “material adverse effect” on the “safety, efficacy, [or] scientific ... or commercial” viability of those Program Compounds as of the date

¹ It is worth noting in this context that, although Abbott apparently understood as of March 2001 that even a one month delay in the commencement of a single clinical trial of a Program Compound was sufficiently “material” to be disclosed to John Hancock, Abbott now takes the position that a *total halt* to all development of a Program Compound, such as ABT-518, was not sufficiently material to disclose at the same time. AFOF, ¶ 84.

of that Agreement and, as shown by events after March 13, 2001, did have a “material adverse effect.” Abbott’s demonstrable material misrepresentations include, but are not limited to:

- ABT-518 - Abbott’s statement that it considered ABT-518 to be a “compelling development candidate,” notwithstanding the fact that Abbott’s senior management had decided to halt all further development of ABT-518 just days before the Agreement was signed due to concerns about the low prospects of success for that compound (HFOF, ¶¶ 68(c), 72(b)-(e));
- ABT-594 - Abbott’s statement that ABT-594 was the subject of a “phase IIb study for neuropathic pain” that “ends in June 2001” and was expected to have “[a] total of 320 patients,” notwithstanding the fact that Abbott already had “prematurely discontinued” that trial two months earlier due to the high patient drop-out rate and with far less than 320 total subjects (*Id.*, ¶¶ 95(c), 98(a)-(k));
- ABT-594 - Abbott’s statement that it planned to spend “35.0” million on the further development of ABT-594 in Calendar Year 2001, including over \$11.5 million for additional Phase II and Phase III clinical studies, notwithstanding the fact that Abbott’s planned spending on ABT-594 in 2001 already had been dramatically reduced by over seventy-three percent (73%) to slightly more than \$9.3 million, and all further clinical trials of that compound already had been “[d]elayed” beyond 2001 before the Agreement was signed (*Id.*, ¶¶ 96, 98(o)-(p));
- ABT-594 - Abbott’s statement that it “expected” ABT-594 “to be the first neuronal nicotinic receptor agonist to receive an indication for pain,” notwithstanding the fact that Abbott’s senior management already had determined, before the Agreement was signed, that Abbott would “probabl[y] T[erminate]” that compound based on the likely results of its recently discontinued Phase IIb trial (*Id.*, ¶¶ 95(e), 98(s)-(u); PLs’ FH);
- ABT-773 - Abbott’s statement that the “likely profile” of ABT-773 would include “[c]onvenience, safety and tolerability” that would be “competitive with [Zithromax],” the existing market leader, notwithstanding the fact that Abbott knew that there were significant, unresolved issues concerning the safety of ABT-773 -- particularly with respect to QT prolongation and liver toxicity -- that were being carefully scrutinized by the FDA (HFOF, ¶¶ 109(c), 115(a)-(b));
- ABT-773 - Abbott’s statement that it “expected” the patient dosing of ABT-773 “to be once-a-day,” notwithstanding the fact that Abbott recognized internally that a “once-a-day formulation [of ABT-773] may not be possible based on the short half-life of the drug and the apparent

short absorption window in the GI tract,” and Abbott still lacked sufficient data to determine whether once-a-day dosing for at least two of the four target indications (CAP and sinusitis) even was viable (*Id.*, ¶¶ 109(b), 115(c)-(d)); and

- ABT-773 - Abbott’s statement that the “likely profile” of ABT-773 would include an “[o]ral suspension form[] enabling penetration into pediatrics,” notwithstanding the fact that Abbott recognized internally that a pediatric formulation would be “very difficult” to achieve, and Abbott’s pediatric formulation project actually was “on hold” and unfunded as of the date of the Agreement (*Id.*, ¶¶ 109(c), 115(e)-(f)).

Abbott’s demonstrable material omissions from the Agreement include, but are not limited to:

- ABT-518 - Abbott’s failure to disclose that its senior management had decided to halt all further development of ABT-518 just days before the Agreement was signed (HFOF, ¶¶ 72(b)-(c));
- ABT-518 - Abbott’s failure to disclose its concerns about the low prospects of success for ABT-518 that were sufficiently material to cause Abbott’s senior management to halt all further development of that compound just days before the Agreement was signed (*Id.*, ¶¶ 72(b)-(e), 76-83; PLs’ BK);
- ABT-518 - Abbott’s failure to disclose that its Phase I trial of ABT-518 only had been ordered recommenced on the day that the Agreement was signed (HFOF, ¶¶ 72(c)-(g));
- ABT-594 - Abbott’s failure to disclose that its Phase IIb trial of ABT-594 had been “prematurely discontinued” by Abbott on account of the high number of drop outs among trial subjects due, primarily, to adverse events involving moderate-to-severe nausea, vomiting and dizziness, as well as “[s]ignificant changes in the developmental strategy of ABT-594” (*Id.*, ¶¶ 98(a)-(l));
- ABT-594 - Abbott’s failure to disclose that its senior management had determined the week before the Agreement was signed that Abbott would “probabl[y] T[erminate]” ABT-594 based on the likely results of its recently discontinued Phase IIb trial (*Id.*, ¶¶ 98(t)-(u)); and
- ABT-773 - Abbott’s failure to disclose significant “[u]nresolved potential safety issues” facing ABT-773 when the Agreement was signed, including the “Key Issues” of potential QT problems and liver toxicity (*Id.*, ¶¶ 115(a)-(b)).

Although Abbott asserts that none of these misrepresentations or omissions was “material” to Hancock’s decision to enter into the Agreement in March 2001 (*see AFOF, ¶¶ 88, 90, 105, 126, 129*), plain common sense dictates otherwise. For example, in assessing the materiality of Dr. Leiden’s undisputed order in early March 2001 directing Abbott personnel to stop work on ABT-518, it seems obvious that Hancock (or any other reasonable investor) would want to know, before sinking millions of dollars of its own money into that compound, that Abbott actually had decided to *halt* the development of ABT-518 *just days before the Agreement was signed.*² The same is true with respect to Abbott’s undeniable decision in late 2000 to decrease its planned spending on ABT-594 in 2001 *by over seventy-three percent (73%)*, or its admitted knowledge in February 2001 that ABT-773 was facing heightened scrutiny by the FDA because of potentially serious QT and liver toxicity problems, which facts, if they had been disclosed to Hancock by Abbott prior to the execution of the Agreement, undoubtedly would have raised serious questions about the condition of, and future prospects for, those compounds. Abbott’s *post facto* assertion that Hancock still would have proceeded with the Agreement in its current form and invested million of dollars in ABT-518, ABT-594 and ABT-773 regardless of the true, significantly more adverse circumstances simply is not credible.

² Abbott’s alternative explanation for stopping and restarting its Phase I trial of ABT-518 in March 2001 (*i.e.*, that Dr. Leiden was “convinced” to proceed with the trial and defer a final decision on the fate of ABT-518 while Abbott awaited information about other competing MMPI compounds that was scheduled to be released at an American Society of Clinical Oncologists (“ASCO”) conference in May 2001) (AFOF, ¶¶ 72(c)-(g)), does not relieve Abbott from liability to John Hancock for misrepresenting the actual condition of, and prospects for, that compound in the Agreement. Neither Abbott’s Descriptive Memorandum for that compound, nor its First ARP make reference to any planned “Go/No Go” decision for ABT-518 in May 2001. To the contrary, Abbott’s First ARP represents that Abbott’s Phase I trial of ABT-518 was not expected to “End” until “1Q/02,” and its Descriptive Memorandum states that “[c]lincial studies [of ABT-518] across a wide range of solid tumors will be initiated [by Abbott], including, but not limited to breast cancer, non small cell lung cancer, ovarian cancer, pancreatic cnacer, etc...” Agreement, Ex. 32 at Exhibit 1.6 (First ARP) and Exhibit 12.2(i) (Descriptive Memoranda). Thus, even Abbott’s “best case” explanation of events provides no defense to John Hancock’s claims in this action.

Abbott assertion that the true condition of, and prospects for, ABT-518, ABT-594 and ABT-773 were not “material” to Hancock’s decision to enter into the Agreement also is inconsistent with the undisputed history of events, as well as the testimony of Abbott’s own witnesses. Abbott knew from experience in the months leading up to the execution of the Agreement that the failure of just one Program Compound (ABT-980) while negotiations still were underway significantly delayed, and almost led to the complete collapse of, the entire Hancock deal. HFOF, ¶¶ 34-37. Abbott learned well from that experience. Mr. Philip Deemer, one of the principal negotiators of the Agreement for Abbott, admitted as much in a March 20, 2001 internal e-mail to Dr. Perry Nisen when he acknowledged that even a “slow down” in the development of ABT-518, if it had been made known to Hancock, “could have been the deathnell [sic] to the deal.” *Id.*, ¶¶ 84-86; PLs’ AD. When questioned further at his deposition regarding the importance of ABT-518 to the proposed Agreement with Hancock, Mr. Deemer testified,

I don’t know what [Hancock’s] view of this was, but it certainly was one of the compounds in the portfolio and that portfolio would have had to have been either constructed differently or something different likely would have needed to be changed in order to keep it on track. *Id.*; Deemer Depo., 103:18-104:3.

The true condition of, and prospects for, ABT-518, ABT-594 and ABT-773 indisputably was information that was material to Hancock’s decision to enter into the Agreement. Had some or all of Abbott’s various misrepresentations or omissions regarding those compounds been made known to Hancock before the execution of the Agreement, that information would have significantly altered the economics and attractiveness of the proposed deal from Hancock’s perspective by, among other things, substantially reducing Hancock’s projected returns and substantially increasing its risk of loss. HFOF, ¶¶ 87-90, 102-105, 125-129. In this context, the

information misrepresented or omitted by Abbott is “so obviously important” that Abbott’s resulting liability for breaching its warranties under the Agreement and defrauding Hancock can and plainly should be determined in Hancock’s favor. HCOL, ¶ 40.

B. *Abbott Defrauded John Hancock And Breached The Agreement By Misrepresenting Its Intended And Reasonably Expected Spending On Program Related Cost In Its ARPs.*

In order to trigger Hancock’s annual Program Payments pursuant to Section 3.1 of the Agreement, Abbott was obligated each year to deliver to Hancock an ARP that demonstrated Abbott’s “intent and reasonable expectation to expend on Program Related Costs during the Program Term an amount in excess of the Aggregate Spending Target.” Agreement, Ex. 32 at § 3.4(iv); HFOF, ¶¶ 131-132. If Abbott ever failed to do so, the Agreement further provides that “John Hancock’s obligation to make any remaining Program Payments for any succeeding Program Years pursuant to Section 3.1 shall terminate.” *Id.*

Abbott fully understands the distinction between “nominal” (*i.e.*, non-risk adjusted) and “expected” (*i.e.*, risk adjusted) spending projections. “Expected” spending projections, because they have been adjusted to try to take account of the risk of failure, typically are lower, sometimes much lower, than “nominal” spending projections, which assume one-hundred percent (100%) success. Hendricks Depo., 110:3-113:19; Woidat Depo., 34:3-34:15.

Discovery in this action has disclosed that Abbott distinguished internally between its “Nominal” and its “Expected” spending on “R&D Costs for [the] John Hancock Compounds.” PLs’ MJ. Discovery also has disclosed, however, that Abbott routinely inflated its planned spending in the various Annual Research Plans that it delivered to Hancock by providing Hancock not with its *expected* spending projections as required under Section 3.4(iv) of the Agreement, but rather with its considerably higher, non-risk adjusted *nominal* spending

projections. Hendricks Depo., 129:22-137:4. Abbott's undisputed misrepresentations in this regard masked the anticipated reductions in its spending on Program Related Costs resulting from the quick failure of various Program Compounds (including ABT-518, ABT-594 and ABT-773), and violated the express terms of the Agreement, thereby triggering the automatic termination of Hancock's obligation to make, at the very least, its Second Program Payment of \$54,000,000 in January 2003. HFOF, ¶¶ 133-136. Hancock seeks, and is entitled to, compensation for that overpayment in this action.

C. *Abbott Breached The Agreement And Concealed Its Fraud Against John Hancock By Intentionally Obstructing And Delaying Hancock's Attempted Compliance Audit Of Abbott In 2004-2005.*

Section 2.5 of the Agreement provides, in part, that,

Abbott shall, and shall cause each Subcontractor to, maintain complete and accurate records ... for purposes of demonstrating compliance with the terms hereof, that fully and properly reflect all work done, results achieved and Program Related Costs expended in performance of the Research Program. The books and records of Abbott and each Subcontractor related to the Research Program ... shall be subject to copying, inspection and audit by (and at the expense of) John Hancock at any time and from time to time. Such audit shall occur on reasonable notice and during normal business hours by an independent auditor selected by John Hancock and reasonably acceptable to Abbott.... In the event that such audit reveals any material breach of Abbott's responsibilities hereunder, Abbott shall (i) pay the reasonable fees and expenses charged by such auditor, and (ii) fully and promptly cure such breach. HFOF, ¶ 155.

On April 12, 2004, Hancock notified Abbott in writing that Hancock was exercising its right under Section 2.5 of the Agreement to audit Abbott's compliance with the Agreement. HFOF, ¶ 156. Rather than cooperate, Abbott responded to Hancock's audit request by engaging in a nearly one-year, protracted, unjustified and unreasonable campaign to hinder, delay and obstruct Hancock's legitimate efforts to examine and assess Abbott's compliance with terms of

the Agreement. *Id.*, ¶¶ 159-166. Abbott's tactics included, but were not limited to: (1) refusing to provide various incriminating "books and records" concerning the true condition of, and prospects for, ABT-518, ABT-594 and ABT-773 that subsequently came to light in the course of discovery in this action; (2) refusing to permit Hancock or its independent auditors to copy any books and records produced during the audit (although "copying" is expressly permitted under Section 2.5), and delaying for six months or more the copying of documents designated for copying by Hancock or its auditors; (3) redacting relevant, incriminating information (and sometimes *all* information) from the documents actually produced to Hancock and its auditors;³ and (4) refusing to answer questions raised by Hancock and its auditors regarding the materials produced (or not produced, as the case may be) during the audit. *Id.*, ¶¶ 160(a)-(n).

As a result of Abbott's successful campaign to conceal its misrepresentations and fraud during Hancock's attempted compliance audit, Hancock not only incurred significant monetary damages associated with the cost of its unsuccessful audit, it also could not, and did not, obtain the information necessary to ascertain the full nature and extent of Abbott's misrepresentations and fraud until it was able to undertake discovery in this litigation.

D. Abbott Breached The Agreement By Refusing To Refund One-Third Of The Unspent Aggregate Carryover Amount To John Hancock.

Abbott also has breached the unambiguous language of Section 3.3(b) of the Agreement by failing to refund to Hancock one-third share of the unspent Aggregate Carryover Amount. HFOF, ¶¶ 141-154. Abbott has refused to make that payment (which varies in size from \$28.3 million to \$33.0 million without interest, depending on which of Abbott's various reports of its

³ An example of a document that Abbott enthusiastically redacted in its entirety is appended to this Trial Memorandum at Tab 4. When this particular document was produced in unredacted form by Abbott in the course of discovery in this action (*see Tab 5*, also PLs' LX), it was found to contain proof that, in early 2001, Abbott had dramatically reduced its planned spending on ABT-594 for all of 2001 well below what Abbott represented it planned to spend on that compound in the Agreement.

actual spending are to be believed) primarily on the ground that it “constitute[s] a penalty clause that is unenforceable under Illinois law.” AFOF, ¶ 153; Abbott’s Supplemental Proposed Findings of Facts and Conclusions of Law (“SAFOF” or “SACOL”), ¶¶ 65-68, 128, 132. Abbott makes this argument notwithstanding the fact that (1) the undisputed evidence shows that Abbott has acknowledged internally that any payment to Hancock under Section 3.3(b) of the Agreement would constitute a partial “refund” of Hancock’s financial contribution to the Research Program, not a penalty (*see* Ex. 30); and (2) in order to qualify as an unenforceable penalty under Illinois law, the “sole purpose” of Section 3.3 must be to enforce Abbott’s performance under the Agreement, which plainly is not the case.⁴ Plaintiffs’ Proposed Additional Findings of Fact and Conclusions of Law (“AHFOF” or “AHCOL”), ¶¶ 50-52 (*quoting* River East Plaza, LLC v. Variable Annuity Life Co., 498 F.3d 718, 722 (7th Cir. 2007)).

Because the “sole purpose” of Section 3.3(b) of the Research Funding Agreement is not to secure Abbott’s performance under that Agreement, it is valid under Illinois law. AHCOL, ¶¶ 53-55. As such, Abbott breached Section 3.3(b) of the Agreement by failing to pay one-third of the unspent Aggregate Carryover Amount to Hancock within thirty (30) days of the end of 2005. HFOF, ¶ 153.

E. Abbott Breached The Agreement By Failing To Maximize The Value Of ABT-518 And ABT-594 For Both Parties After Abbott Substantially Ceased Developing Those Compounds.

Hancock’s financial interest in a Program Compound does not end if Abbott ceases to develop that compound. Program Compounds that Abbott has “substantially cease[d]

⁴ At least one other undeniable purpose of Section 3.3(b) is to allow John Hancock to recover a portion of its investment in Abbott’s Research Program in the event that Abbott’s actual aggregate spending through 2005 falls below \$614 million.

developing, marketing or selling” are defined in Section 4.3(c) of the Agreement as “Ceased Compounds.” HFOF, ¶ 167. Section 4.3(d) of the Agreement further provides that, “as soon as is practicable, Abbott *shall* maximize the commercial value, if any, of [a] Ceased Compound *to both parties* by out-licensing or divesting such Ceased Compound to a third party.” *Id.* (emphasis added). After Abbott has out-licensed or divested the Ceased Compound to a third party, Abbott must “remunerate John Hancock based on sales of such Ceased Compound by the third party … in a manner most consistent with the allocation that would have applied … in accordance with the royalties and milestones payable hereunder.” *Id.*

Abbott does not dispute that ABT-518 and ABT-594 qualify as “Ceased Compounds” under the Agreement. AFOF, ¶¶ 168, 171. Notwithstanding that fact, Abbott has not out-licensed or divested either ABT-518 or ABT-594 to a third party as required under Section 4.3(d) in the more than *six years* that have passed since Abbott ceased developing them. AFOF, ¶¶ 169, 172. To the contrary, evidence obtained in discovery establishes that Abbott’s management affirmatively has *blocked* any out-licensing of ABT-594 for Abbott’s own business purposes (and to Hancock’s financial detriment) because Abbott currently has another, replacement NNR compound (ABT-894) in development, and Abbott “would not want [a] competing program” involving ABT-594 undertaken by another pharmaceutical company “with [the] potential for diversion” that it might cause in the marketplace. HFOF, ¶ 176; PLs’ KD.

Abbott’s failure to out-license or otherwise divest either ABT-518 or ABT-594 to a third party “as soon as practicable” constitutes a further breach of the Agreement that has further deprived Hancock of the “royalties and milestones payable [t]hereunder.”

II. THE EVIDENCE PROVIDES A REASONABLE BASIS TO AWARD JOHN HANCOCK ITS ACTUAL DAMAGES OR, ALTERNATIVELY, TO RESCIND THE AGREEMENT IN ITS ENTIRETY.

Hancock's damage expert, Mr. Alan Friedman of CRA International, Inc., has calculated Hancock's actual damages resulting from Abbott's various violations of the Agreement and fraud. PLs' QH. Mr. Friedman made his calculations using what Abbott admits is the "best available data," and employing methodologies that have been sanctioned as "reasonably reliable" by various accounting organizations and that are regularly used by Abbott itself in the course of its own business.

This Court already has heard and rejected Abbott's various arguments that Mr. Friedman's calculations are "unprecedented," "inherently speculative," "not calculated to a reasonable certainty," and "based on erroneous assumptions" when it considered and denied Abbott's Motion In Limine To Exclude The Expert Testimony Of Mr. Alan Friedman in November 2007. ACOL, ¶¶ 8, 27. Hancock will prove at trial that Mr. Friedman's damage calculations are well-founded and fully satisfy Hancock's burden of proof under Illinois law. HCOL, ¶¶ 8, 27 (*citing De Koven Drug Co. v. First Nat. Bank of Evergreen Park*, 27 Ill.App.3d 798, 802 (1st Dist. 1975) ("once the existence of damage is established, evidence tending to reasonably approximate the extent of the damage is admissible. Absolute certainty as to the amount of damage in such cases is not required to justify a recovery. It is only necessary that the evidence tend to establish a basis for the assessment of damages with a fair degree of probability."). Hancock also will prove that Abbott's various material misrepresentations, omissions and fraud justify rescission of the entire Agreement as an alternative remedy. *Id.*, ¶¶ 39-40 (*citing C3 Technologies, Inc. v. Fontana Machine & Engineering Co.*, 1992 WL 97712, at *4 (N.D. Ill. May 1, 1992) (rescission is an appropriate remedy where the demonstrated

breach is “of such a nature and of such importance that the contract would not have been made without it.”).

III. ABBOTT’S AFFIRMATIVE DEFENSES DO NOT BAR JOHN HANCOCK’S CLAIMS OR PRAYER FOR RESCISSION.

Abbott has raised a series of affirmative defenses to Hancock’s claims, and its prayer for rescission in particular, including judicial estoppel, waiver, laches, delay and ratification. SACOL, ¶¶ 69-127. None of those defenses has any merit given that: (1) during *Hancock I*, this Court stated, and Abbott expressly acknowledged, that Hancock’s claims against Abbott would be limited to determining Hancock’s Program Payment obligations; (2) Abbott has, on multiple occasions during *Hancock II*, knowingly waived its objections to Hancock’s rescission claim; and (3) Abbott cannot assert untimeliness when its own active efforts to conceal its fraud, including during Hancock’s audit, caused the purported delay. AHFOF ¶¶ 1-24; AHCOL, ¶ 34. Furthermore, Abbott’s contention that Article 11 of the Agreement precludes rescission contradicts the plain language of that provision, as well as Illinois law holding such exculpatory clauses to be void as a matter of law. AHFOF, ¶¶ 25-26; AHCOL, ¶¶ 41-42.

Conclusion

For the foregoing reasons, John Hancock respectfully requests that this Court: (1) find in favor of John Hancock on Counts I-III of its Second Amended Supplemental Complaint; (2) grant John Hancock the actual and punitive damages it seeks as a remedy for Abbott’s fraud and material breaches of contract or, in the alternative, order rescission of the Research Funding Agreement in its entirety; and (3) grant such further relief as the Court deems appropriate.

JOHN HANCOCK LIFE INSURANCE
COMPANY, JOHN HANCOCK VARIABLE
LIFE INSURANCE COMPANY and
MANULIFE INSURANCE COMPANY

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Date: February 18, 2008

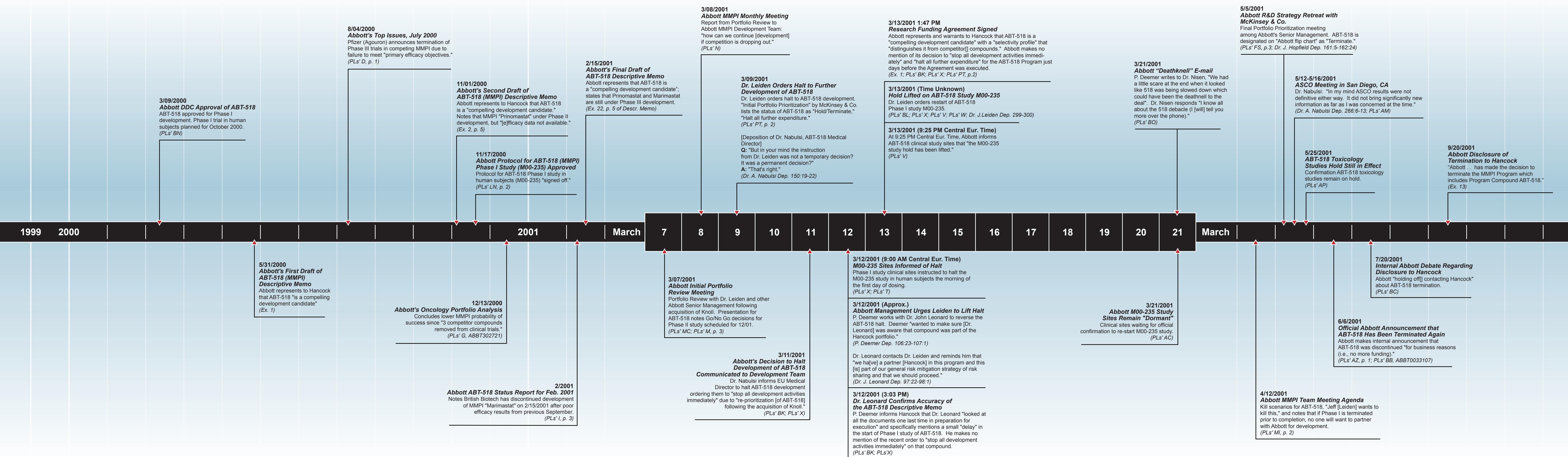
CERTIFICATE OF SERVICE

I hereby certify that this document is being filed with the Court through the ECF system and that a copy will be sent electronically to counsel for defendant through the ECF system on February 18, 2008.

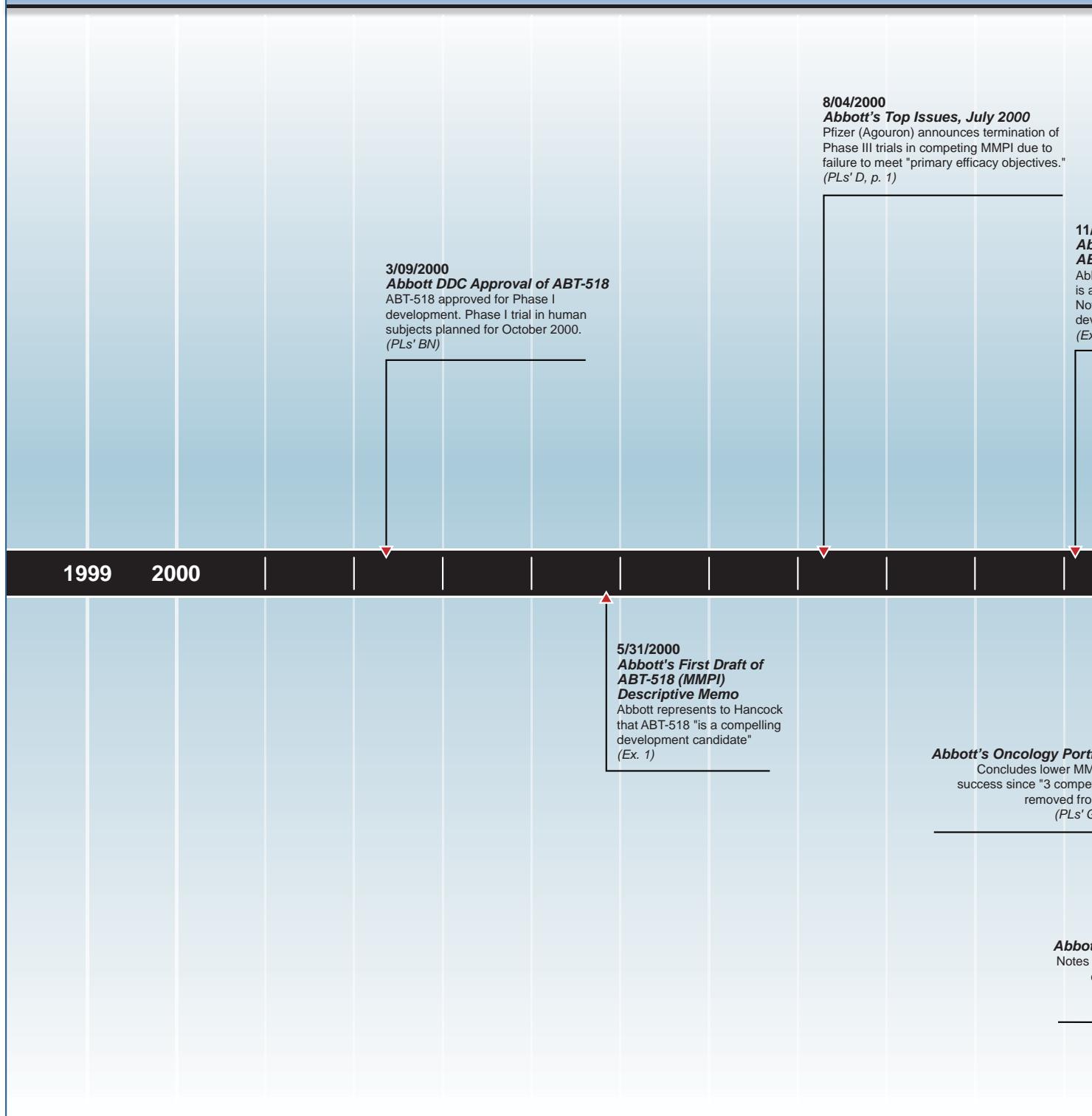
/s/ Richard C. Abati
Richard C. Abati (BBO No. 651037)

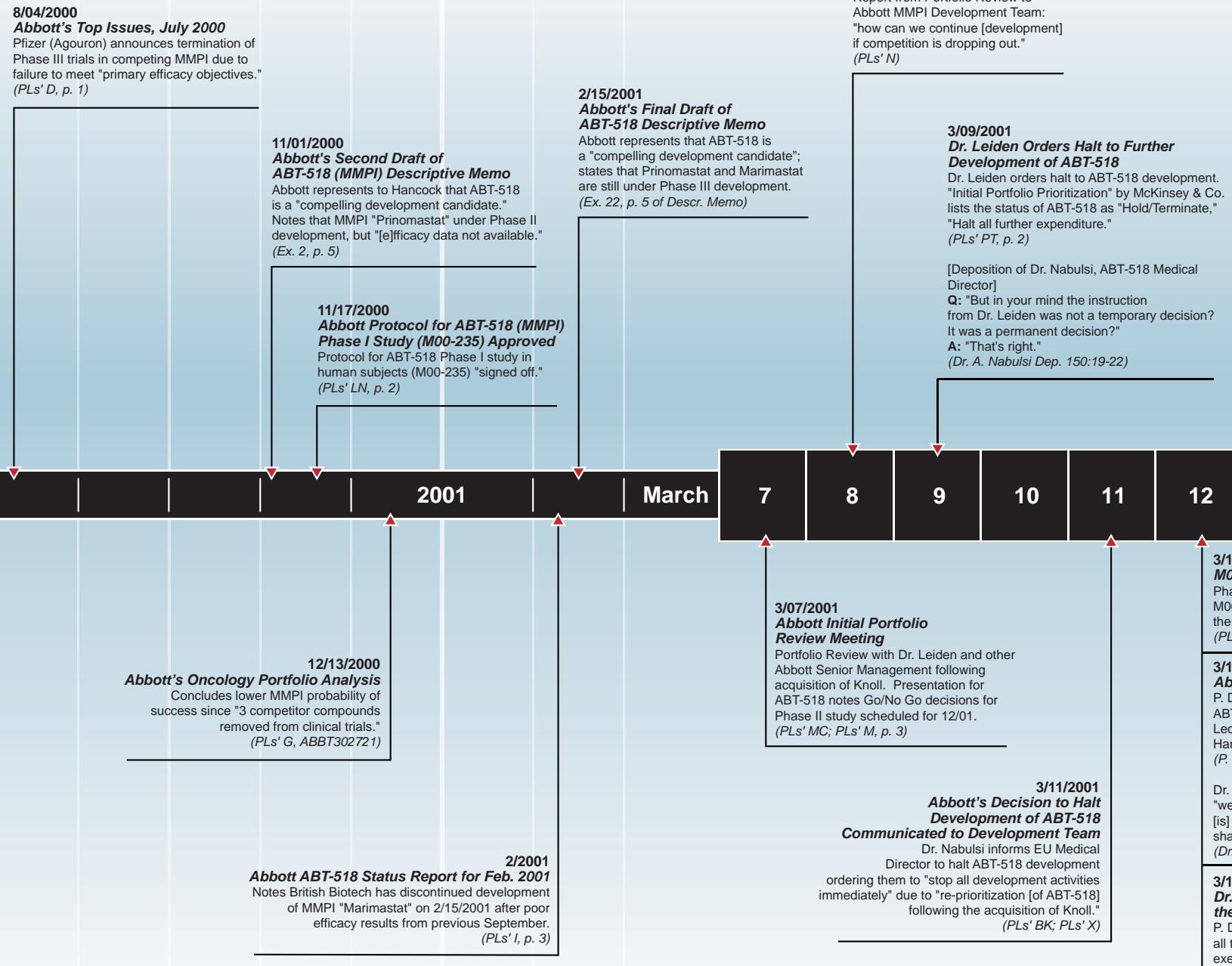
Tab 1

ABT-518 (MMPI) Timeline



ABT-518 (MMPI) Timeline





Monthly Meeting
Portfolio Review to
Development Team:
Continue [development]
dropping out."

3/09/2001

Dr. Leiden Orders Halt to Further Development of ABT-518

Dr. Leiden orders halt to ABT-518 development.
"Initial Portfolio Prioritization" by McKinsey & Co. lists the status of ABT-518 as "Hold/Terminate," "Halt all further expenditure."

(PLs' PT, p. 2)

[Deposition of Dr. Nabulsi, ABT-518 Medical Director]

Q: "But in your mind the instruction from Dr. Leiden was not a temporary decision? It was a permanent decision?"

A: "That's right."

(Dr. A. Nabulsi Dep. 150:19-22)

3/13/2001 1:47 PM

Research Funding Agreement Signed

Abbott represents and warrants to Hancock that ABT-518 is a "compelling development candidate" with a "selectivity profile" that "distinguishes it from competitor[] compounds." Abbott makes no mention of its decision to "stop all development activities immediately" and "halt all further expenditure" for the ABT-518 Program just days before the Agreement was executed.

(Ex. 1; PLs' BK; PLs' X; PLs' PT, p.2)

3/13/2001 (Time Unknown)

Hold Lifted on ABT-518 Study M00-235

Dr. Leiden orders restart of ABT-518 Phase I study M00-235.

(PLs' BL; PLs' X; PLs' V; PLs' W; Dr. J. Leiden Dep. 299-300)

3/13/2001 (9:25 PM Central Eur. Time)

At 9:25 PM Central Eur. Time, Abbott informs ABT-518 clinical study sites that "the M00-235 study hold has been lifted."

(PLs' V)

3/21/2001

Abbott "Deathknell" E-mail

P. Deemer writes to Dr. Nisen, "We had a little scare at the end when it looked like 518 was being slowed down which could have been the deathknell to the deal". Dr. Nisen responds "I know all about the 518 debacle (I [will] tell you more over the phone)."

(PLs' BO)

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March

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ation for
cisions for
12/01.

3/11/2001
Abbott's Decision to Halt Development of ABT-518
1 to Development Team

Nabulsi informs EU Medical
halt ABT-518 development
op all development activities
e-prioritization [of ABT-518]
ing the acquisition of Knoll."

(PLs' BK; PLs' X)

3/12/2001 (9:00 AM Central Eur. Time)
M00-235 Sites Informed of Halt

Phase I study clinical sites instructed to halt the M00-235 study in human subjects the morning of the first day of dosing.

(PLs' X; PLs' T)

3/12/2001 (Approx.)

Abbott Management Urges Leiden to Lift Halt
P. Deemer works with Dr. John Leonard to reverse the ABT-518 halt. Deemer "wanted to make sure [Dr. Leonard] was aware that compound was part of the Hancock portfolio."
(P. Deemer Dep. 106:23-107:1)

Dr. Leonard contacts Dr. Leiden and reminds him that "we ha[ve] a partner [Hancock] in this program and this [is] part of our general risk mitigation strategy of risk sharing and that we should proceed."

(Dr. J. Leonard Dep. 97:22-98:1)

3/12/2001 (3:03 PM)

Dr. Leonard Confirms Accuracy of the ABT-518 Descriptive Memo

P. Deemer informs Hancock that Dr. Leonard "looked at all the documents one last time in preparation for execution" and specifically mentions a small "delay" in the start of Phase I study of ABT-518. He makes no mention of the recent order to "stop all development activities immediately" on that compound.

(PLs' BK; PLs' X)

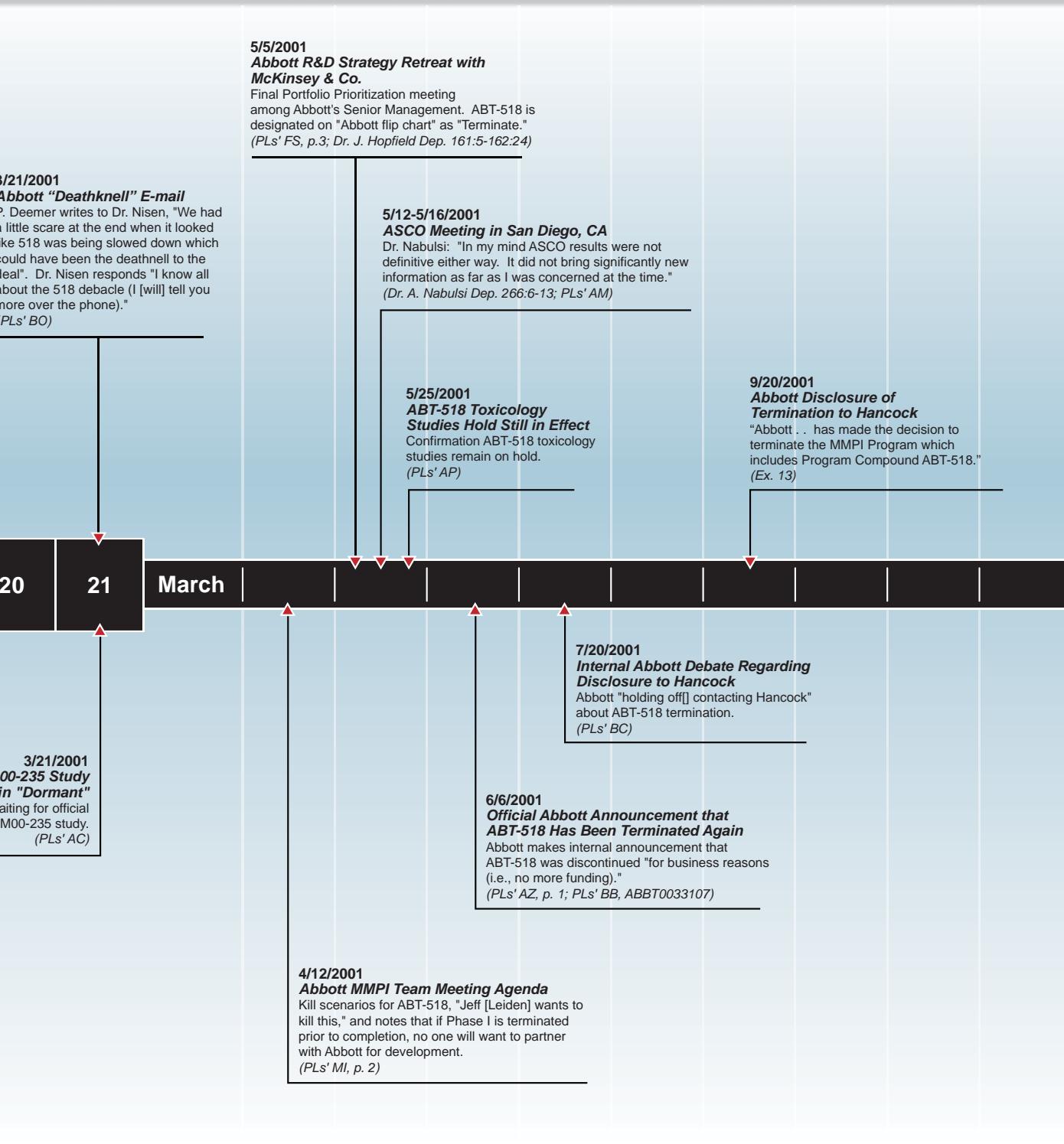
3/21/2001

Abbott M00-235 Study Sites Remain "Dormant"

Clinical sites waiting for official confirmation to re-start M00-235 study.

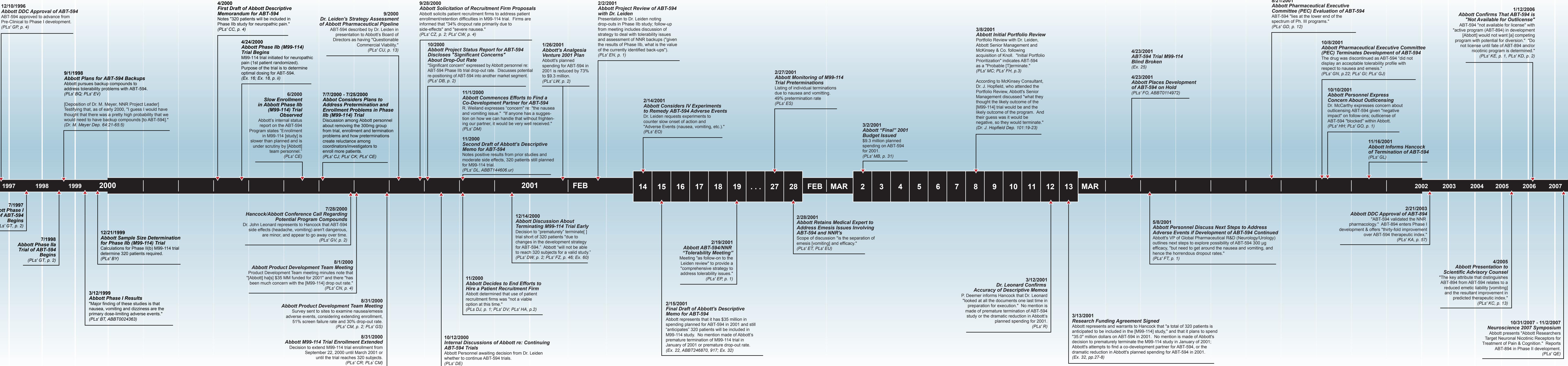
(PLs' AC)

5/5/2001
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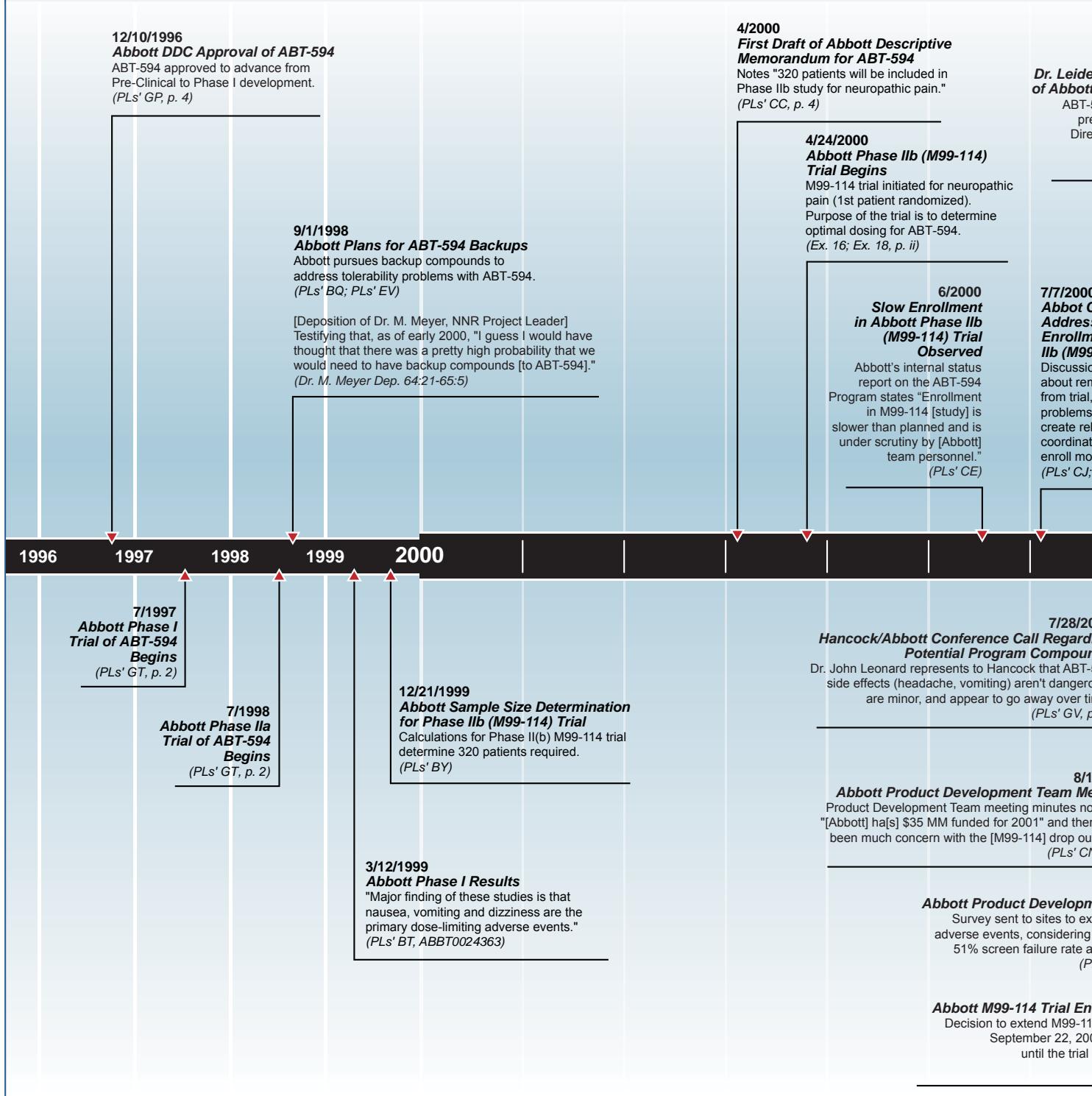


Tab 2

ABT-594 (NNR) Timeline



ABT-594 (NNR) Timeline



**of Abbott Descriptive
Sum for ABT-594**

patients will be included in study for neuropathic pain."
(4)

4/24/2000**Abbott Phase IIb (M99-114)****Trial Begins**

M99-114 trial initiated for neuropathic pain (1st patient randomized). Purpose of the trial is to determine optimal dosing for ABT-594.
Ex. 16; Ex. 18, p. ii)

6/2000
**Slow Enrollment
in Abbott Phase IIb
(M99-114) Trial
Observed**

Abbott's internal status report on the ABT-594 Program states "Enrollment in M99-114 [study] is slower than planned and is under scrutiny by [Abbott] team personnel."
(PLs' CE)

9/2000
**Dr. Leiden's Strategy Assessment
of Abbott Pharmaceutical Pipeline**

ABT-594 described by Dr. Leiden in presentation to Abbott's Board of Directors as having "Questionable Commercial Viability."
(PLs' CU, p. 13)

7/7/2000 - 7/25/2000
**Abbot Considers Plans to
Address Pretermination and
Enrollment Problems in Phase
IIb (M99-114) Trial**

Discussion among Abbott personnel about removing the 300mg group from trial, enrollment and termination problems and how preterminations create reluctance among coordinators/investigators to enroll more patients.
(PLs' CJ; PLs' CK; PLs' CE)

9/28/2000**Abbott Solicitation of Recruitment Firm Proposals**

Abbott solicits patient recruitment firms to address patient enrollment/retention difficulties in M99-114 trial. Firms are informed that "34% dropout rate primarily due to side-effects" and "severe nausea."
(PLs' CZ, p. 2; PLs' CW, p. 4)

10/2000**Abbott Project Status Report for ABT-594
Discloses "Significant Concerns"
About Drop-Out Rate**

"Significant concern" expressed by Abbott personnel re: ABT-594 Phase IIb trial drop-out rate. Discusses potential re-positioning of ABT-594 into another market segment.
(PLs' DB, p. 2)

1/26/2001**Abbott's Analgesia
Venture 2001 Plan**

Abbott's planned spending for ABT-594 in 2001 is reduced by 73% to \$9.3 million.
(PLs' LW, p. 2)

2/2/2001**Abbott Project Review of ABT-594
with Dr. Leiden**

Presentation to Dr. Leiden noting drop-outs in Phase IIb study; focus of meeting includes discussion strategy to deal with tolerability and assessment of NNR backup the results of Phase IIb, what is of the currently identified back-up
(PLs' EN, p. 1)

2/14/2001
Abbott's
to Remake
Dr. Leiden
counter
"Adversary
(PLs' EN)

7/28/2000
**Hancock/Abbott Conference Call Regarding
Potential Program Compounds**

Dr. John Leonard represents to Hancock that ABT-594 side effects (headache, vomiting) aren't dangerous, are minor, and appear to go away over time.
(PLs' GV, p. 2)

8/1/2000**Abbott Product Development Team Meeting**

Product Development Team meeting minutes note that "[Abbott] ha[s] \$35 MM funded for 2001" and there "has been much concern with the [M99-114] drop out rate."
(PLs' CN, p. 4)

8/31/2000**Abbott Product Development Team Meeting**

Survey sent to sites to examine nausea/emeisis adverse events, considering extending enrollment, 51% screen failure rate and 30% drop-out rate.
(PLs' CM, p. 2; PLs' GS)

8/31/2000**Abbott M99-114 Trial Enrollment Extended**

Decision to extend M99-114 trial enrollment from September 22, 2000 until March 2001 or until the trial reaches 320 subjects.
(PLs' CR; PLs' CM)

11/1/2000**Abbott Commences Efforts to Find a
Co-Development Partner for ABT-594**

R. Weiland expresses "concern" re: "the nausea and vomiting issue." "If anyone has a suggestion on how we can handle that without frightening our partner, it would be very well received."
(PLs' DM)

11/2000**Second Draft of Abbott's Descriptive
Memo for ABT-594**

Notes positive results from prior studies and moderate side effects, 320 patients still planned for M99-114 trial.
(PLs' DL, ABBT144606.ur)

2001**FEB****14****12/14/2000**
**Abbott Discussion About
Terminating M99-114 Trial Early**

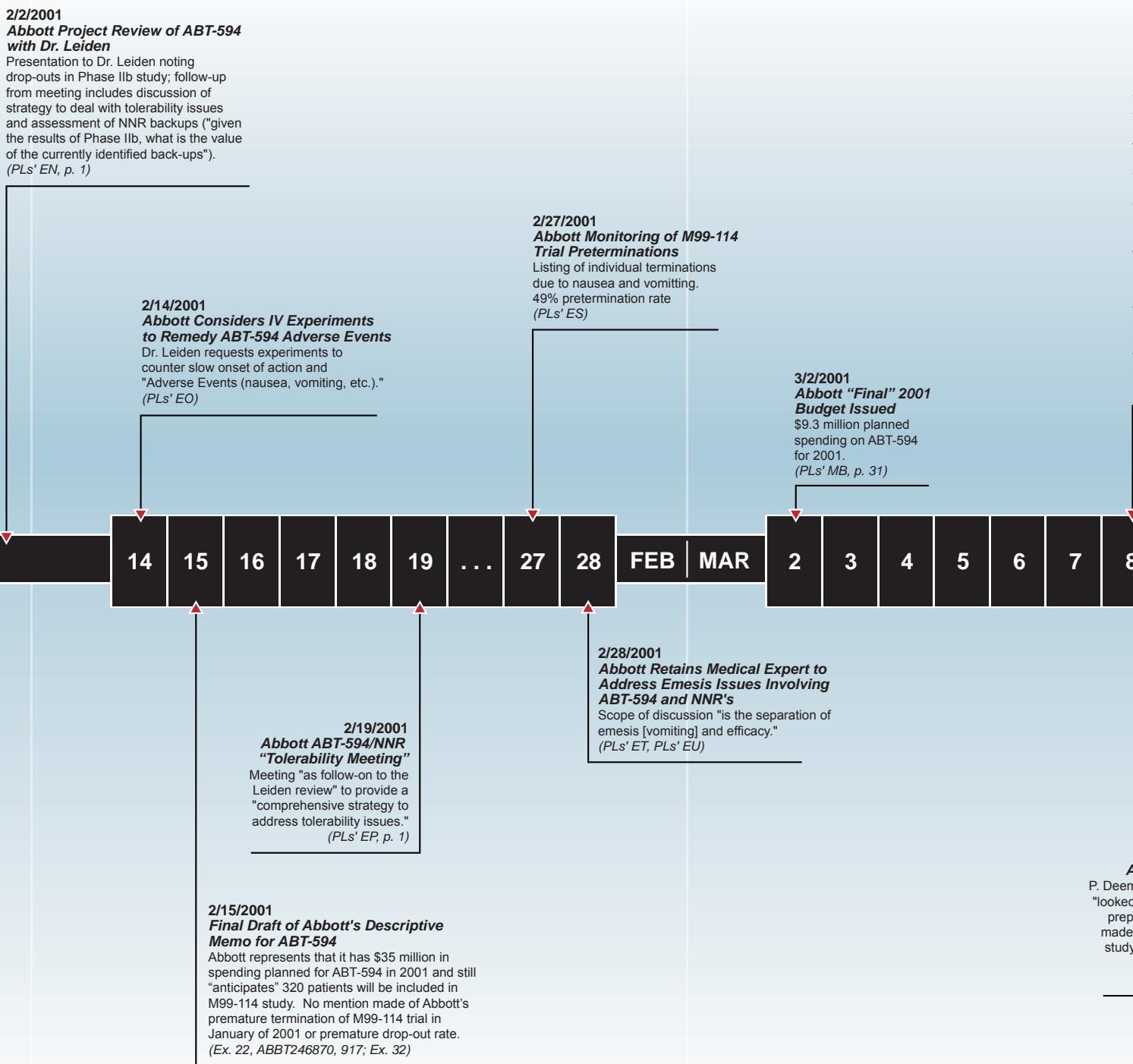
Decision to "prematurely" terminate[] trial short of 320 patients "due to changes in the development strategy for ABT-594." Abbott "will not be able to reach 320 subjects for a valid study."
(PLs' DW, p. 2; PLs' FZ, p. 46; Ex. 60)

11/2000**Abbott Decides to End Efforts to
Hire a Patient Recruitment Firm**

Abbott determined that use of patient recruitment firms was "not a viable option at this time."
(PLs' DJ, p. 1; PLs' DV; PLs' HA, p.2)

10/12/2000**Internal Discussions of Abbott re: Continuing
ABT-594 Trials**

Abbott Personnel awaiting decision from Dr. Leiden whether to continue ABT-594 trials.
(PLs' DE)



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 "Final" 2001
 t Issued
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 g on ABT-594
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 3, p. 31)

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MAR

3/8/2001**Abbott Initial Portfolio Review**

Portfolio Review with Dr. Leiden, Abbott Senior Management and McKinsey & Co. following acquisition of Knoll. "Initial Portfolio Prioritization" indicates ABT-594 as a "Probable [T]erminate." (PLs' MC; PLs' FH, p.3)

According to McKinsey Consultant, Dr. J. Hopfield, who attended the Portfolio Review, Abbott's Senior Management discussed "what they thought the likely outcome of the [M99-114] trial would be and the likely outcome of the program. And their guess was it would be negative, so they would terminate." (Dr. J. Hopfield Dep. 101:19-23)

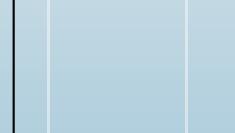
**4/23/2001****ABT-594 Trial M99-114**

Blind Broken
 (Ex. 25)

4/23/2001**Abbott Places Development**

of ABT-594 on Hold

(PLs' FO, ABBT0114972)

**5/8/2001****Abbott Personnel Discuss Next Steps to Address**

Adverse Events if Development of ABT-594 Continued
 Abbott's VP of Global Pharmaceutical R&D (Neurology/Urology) outlines next steps to explore possibility of ABT-594 300 µg efficacy, "but need to get around the nausea and vomiting, and hence the horrendous dropout rates."
 (PLs' FT, p. 1)

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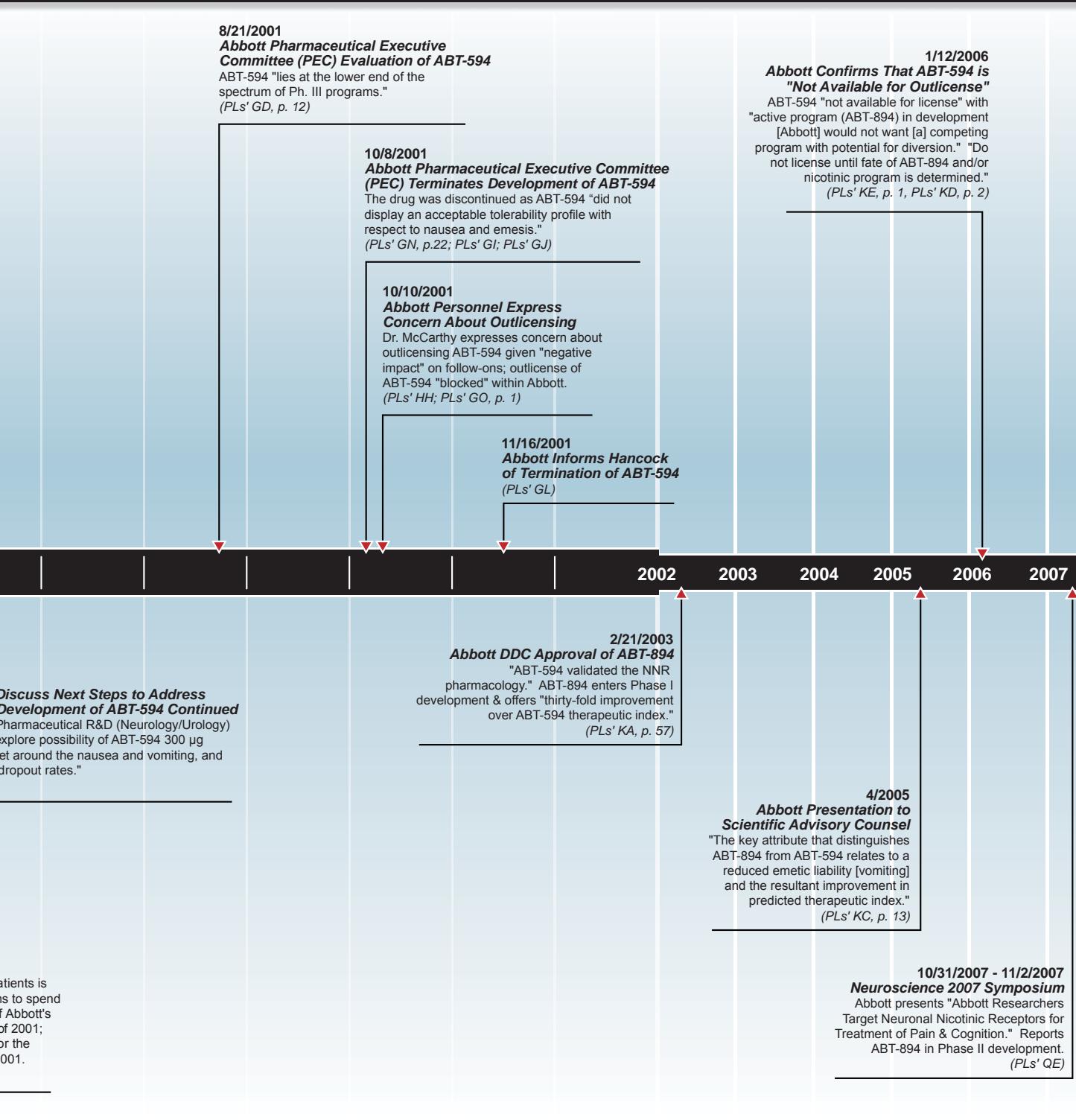
3/12/2001**Dr. Leonard Confirms Accuracy of Descriptive Memos**

P. Deemer informs Hancock that Dr. Leonard "looked at all the documents one last time in preparation for execution." No mention is made of premature termination of ABT-594 study or the dramatic reduction in Abbott's planned spending for 2001. (PLs' R)

3/13/2001**Research Funding Agreement Signed**

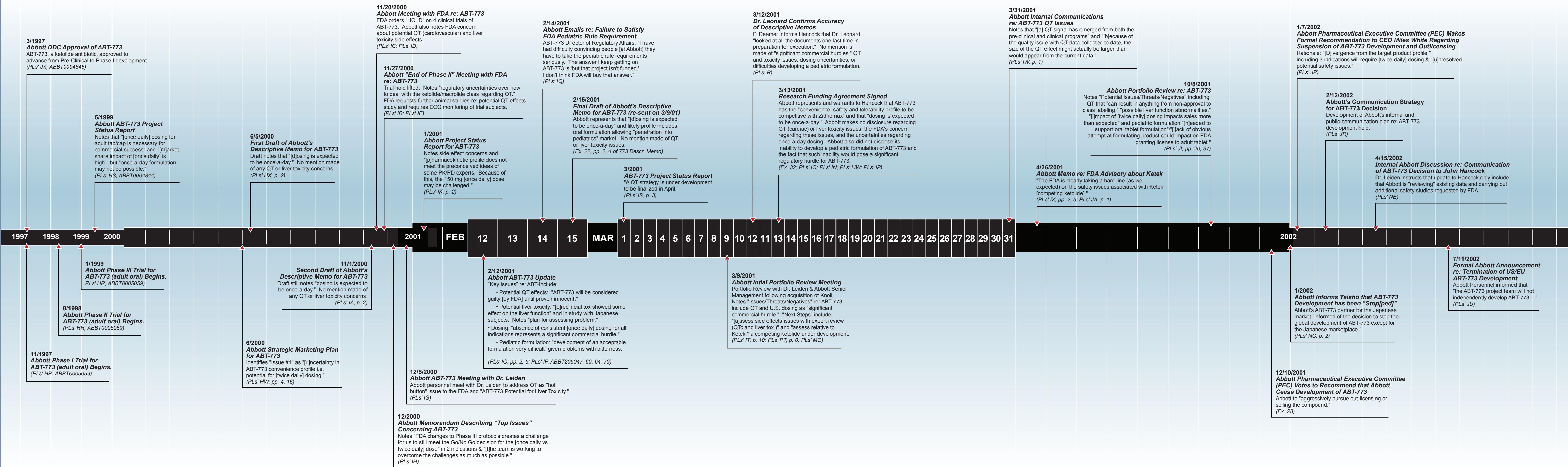
Abbott represents and warrants to Hancock that "a total of 320 patients is anticipated to be included in the [M99-114] study," and that it plans to spend "35.0" million dollars on ABT-594 in 2001. No mention is made of Abbott's decision to prematurely terminate the M99-114 study in January of 2001; Abbott's attempts to find a co-development partner for ABT-594, or the dramatic reduction in Abbott's planned spending for ABT-594 in 2001. (Ex. 32, pp.27-8)

8/21/2001
Abbott Ph Committee
 ABT-594 "lie spectrum of (PLs' GD, p.

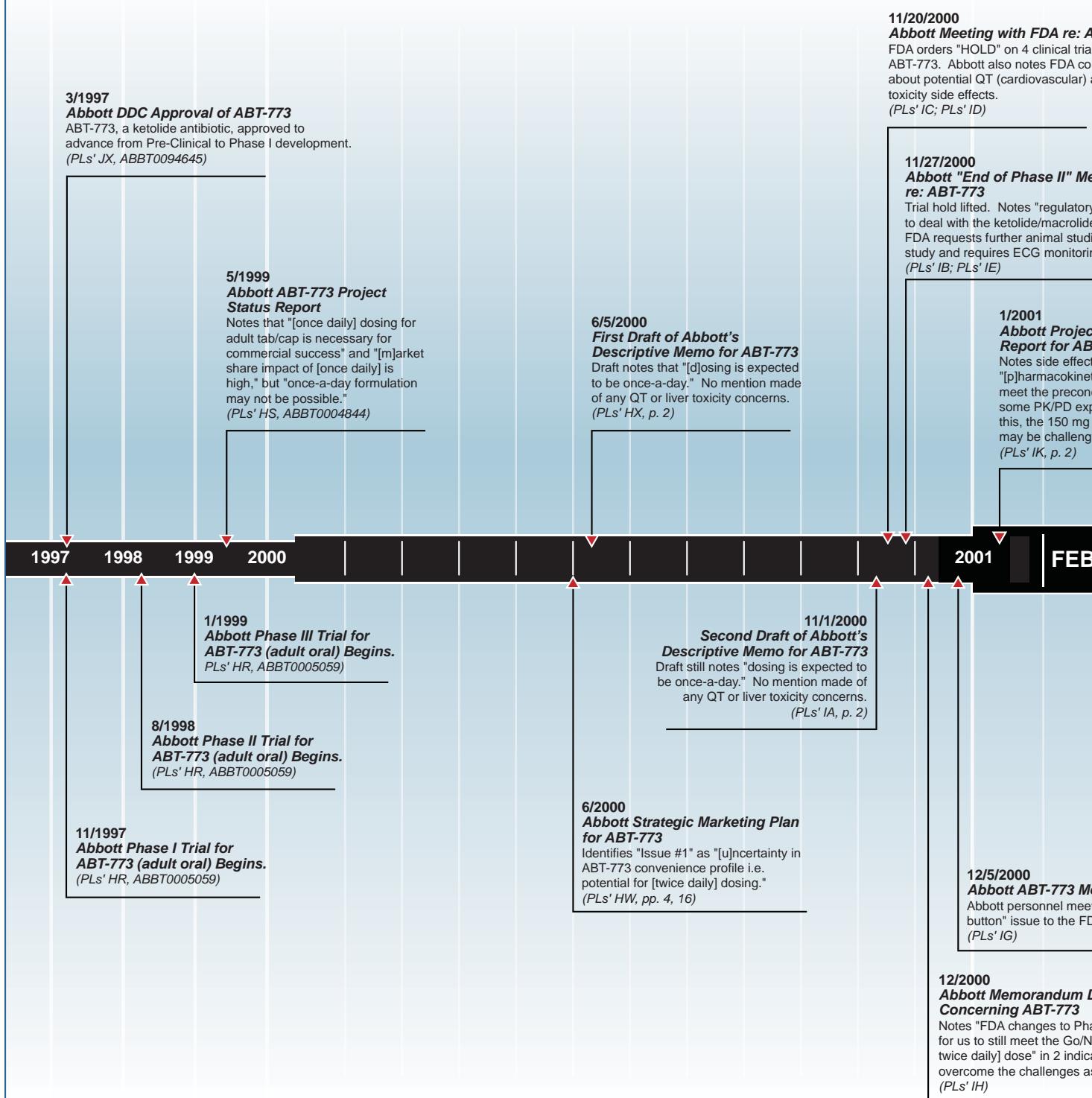


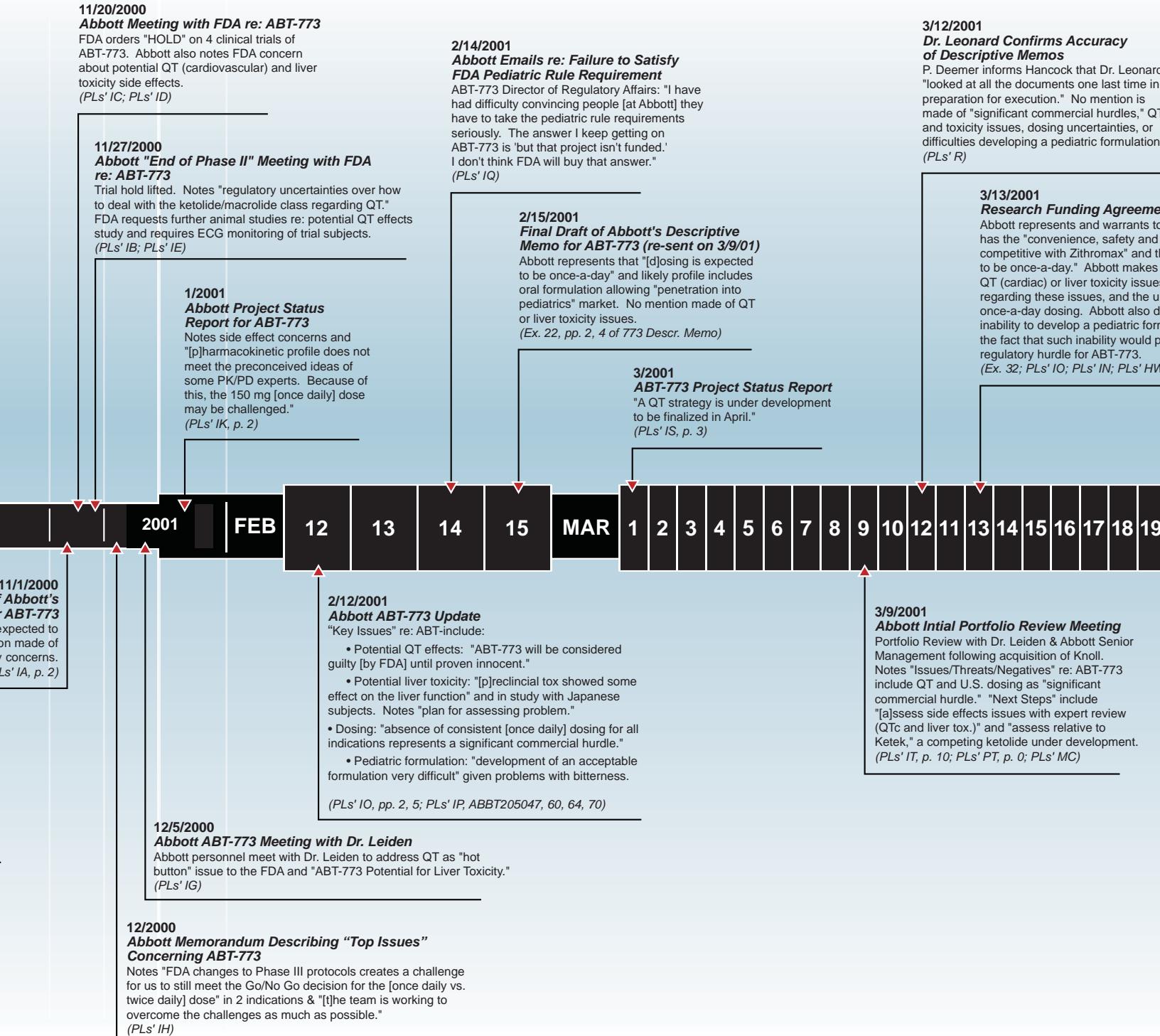
Tab 3

ABT-773 (ketolide) Timeline



ABT-773 (ketolide) Timeline





3/12/2001

**Dr. Leonard Confirms Accuracy
of Descriptive Memos**

P. Deemer informs Hancock that Dr. Leonard "looked at all the documents one last time in preparation for execution." No mention is made of "significant commercial hurdles," QT and toxicity issues, dosing uncertainties, or difficulties developing a pediatric formulation. (PLs' R)

3/13/2001

Research Funding Agreement Signed

Abbott represents and warrants to Hancock that ABT-773 has the "convenience, safety and tolerability profile to be competitive with Zithromax" and that "dosing is expected to be once-a-day." Abbott makes no disclosure regarding QT (cardiac) or liver toxicity issues, the FDA's concern regarding these issues, and the uncertainties regarding once-a-day dosing. Abbott also did not disclose its inability to develop a pediatric formulation of ABT-773 and the fact that such inability would pose a significant regulatory hurdle for ABT-773.

(Ex. 32; PLs' IO; PLs' IN; PLs' HW; PLs' IP)

3/31/2001

**Abbott Internal Communications
re: ABT-773 QT Issues**

Notes that "[a] QT signal has emerged from both the pre-clinical and clinical programs" and "[b]ecause of the quality issue with QT data collected to date, the size of the QT effect might actually be larger than would appear from the current data."

(PLs' IW, p. 1)

10/8/2001

Abbott Portfolio Review re: ABT-773

Notes "Potential Issues/Threats/Negatives" including: QT that "can result in anything from non-approval to class labeling," "possible liver function abnormalities," "[i]mpact of [twice daily] dosing impacts sales more than expected" and pediatric formulation "[n]eeded to support oral tablet formulation" "[l]ack of obvious attempt at formulating product could impact on FDA granting license to adult tablet."

(PLs' JI, pp. 20, 37)

4/26/2001

Abbott Memo re: FDA Advisory about Ketek

"The FDA is clearly taking a hard line (as we expected) on the safety issues associated with Ketek [competing ketolide]."

(PLs' IX, pp. 2, 5; PLs' JA, p. 1)

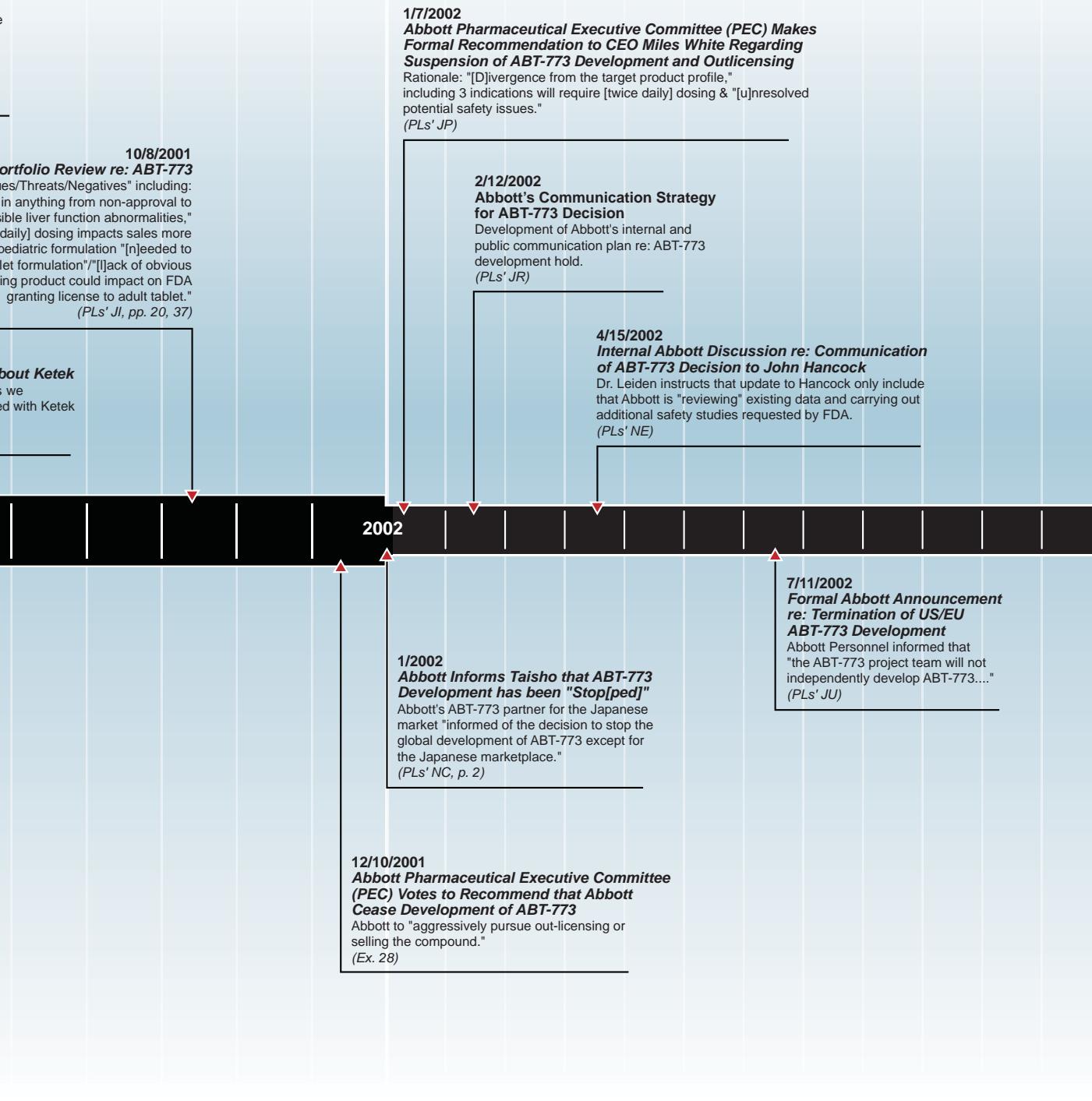
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10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

9/2001

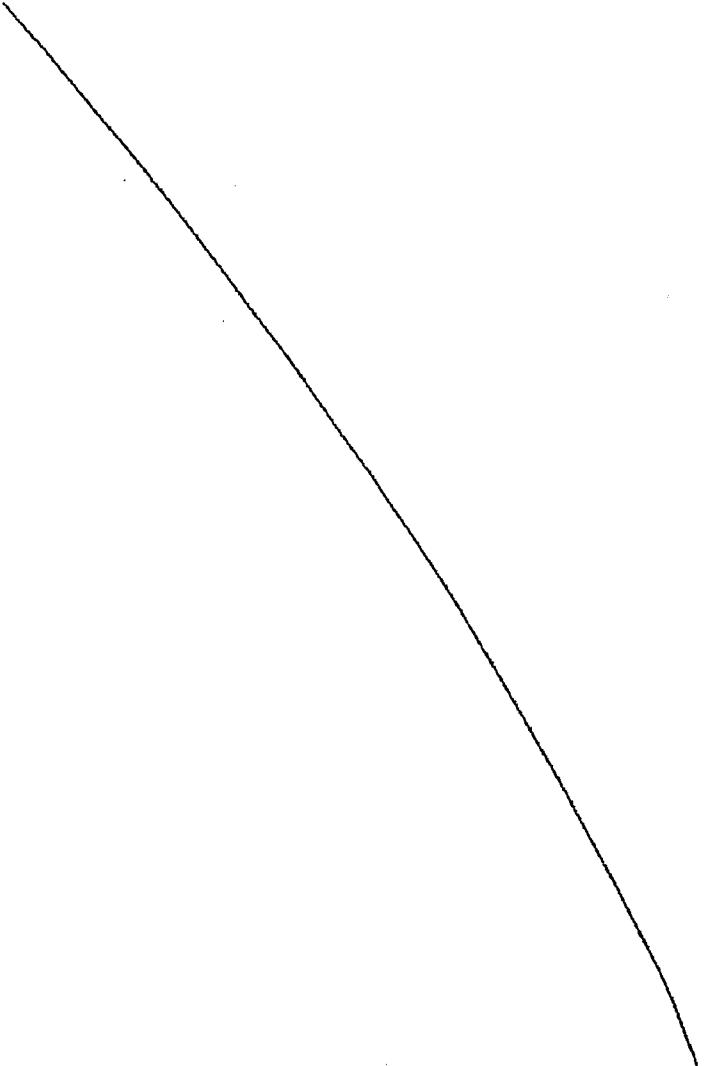
Abbott Intial Portfolio Review Meeting

Portfolio Review with Dr. Leiden & Abbott Senior Management following acquisition of Knoll. Notes "Issues/Threats/Negatives" re: ABT-773 include QT and U.S. dosing as "significant commercial hurdle." "Next Steps" include "assess side effects issues with expert review (TC and liver tox.)" and "assess relative to Ketek," a competing ketolide under development. (PLs' IT, p. 10; PLs' PT, p. 0; PLs' MC)



Tab 4

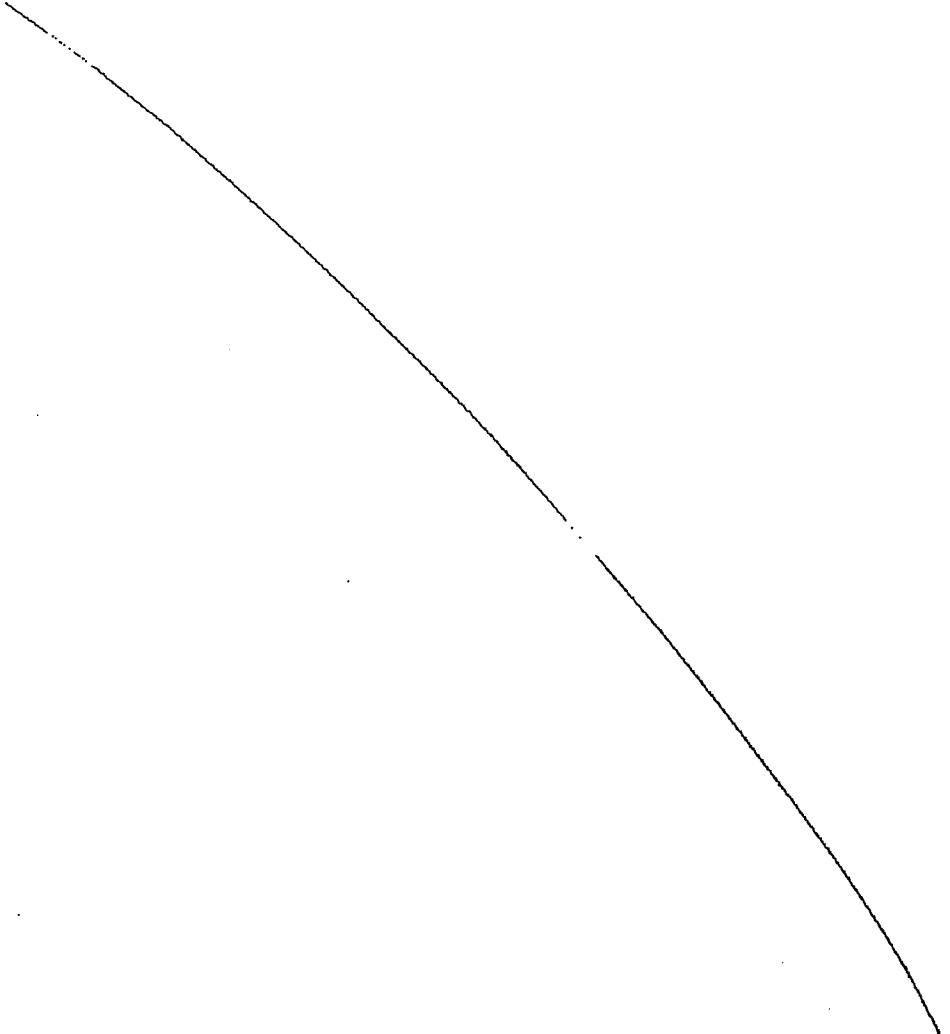
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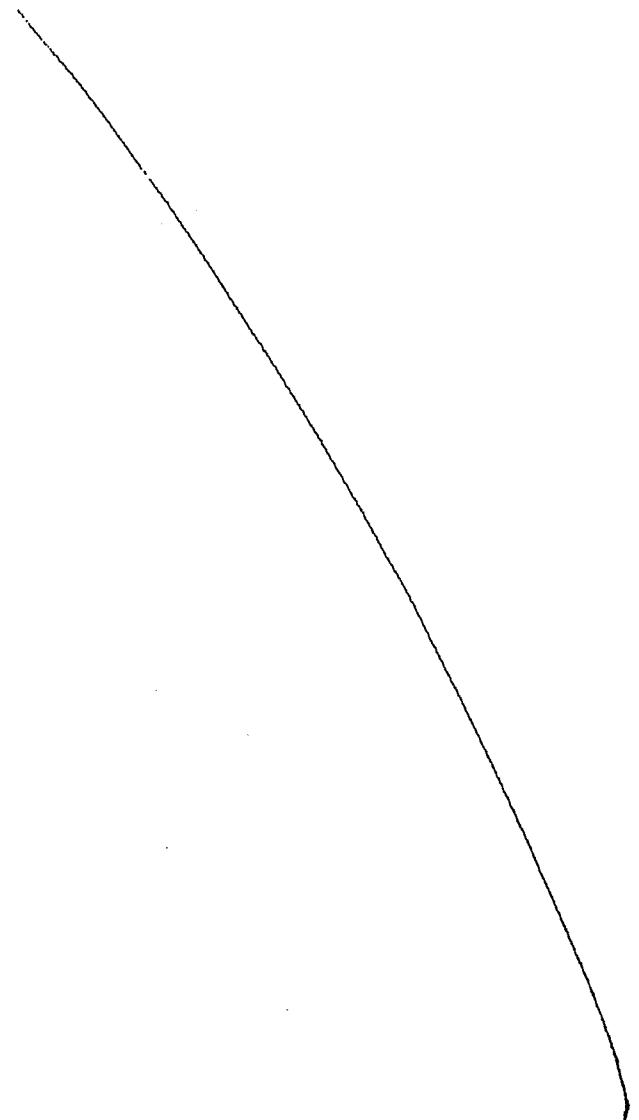
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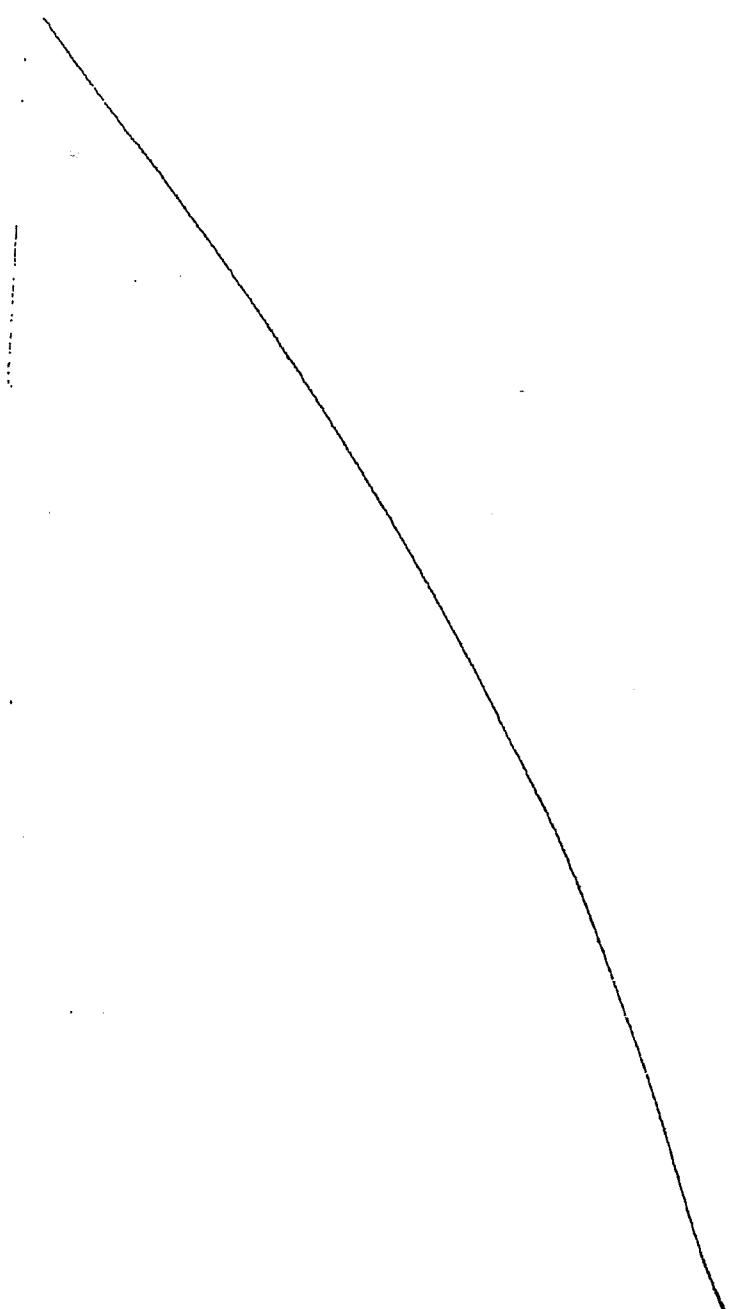
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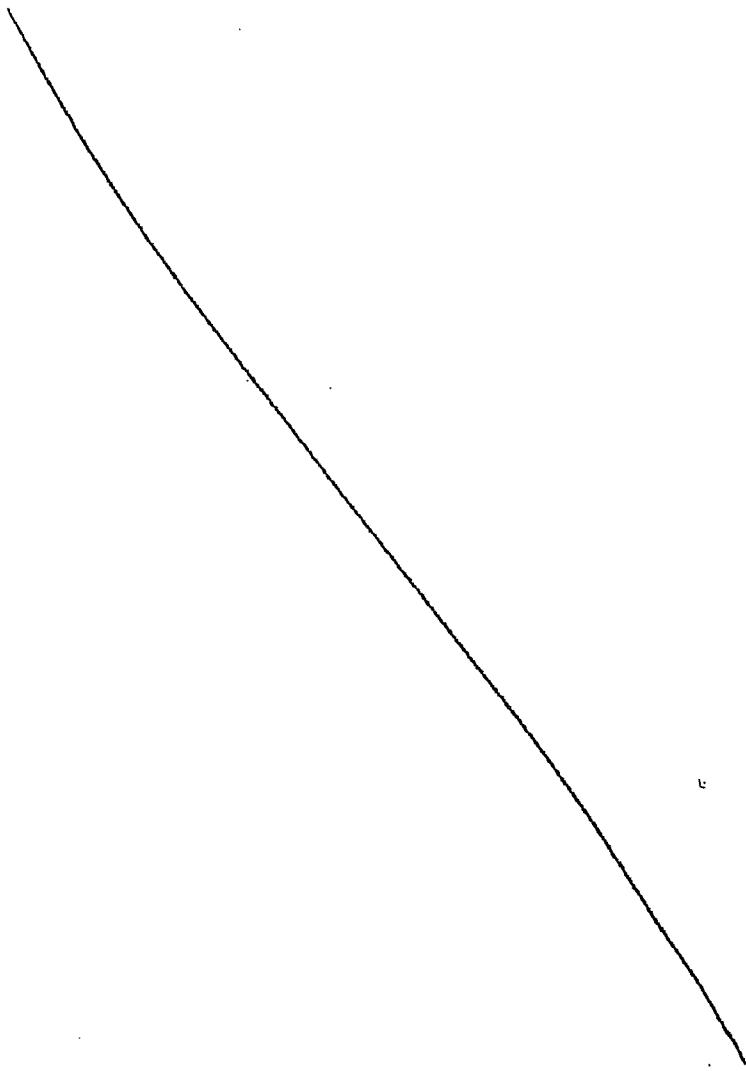
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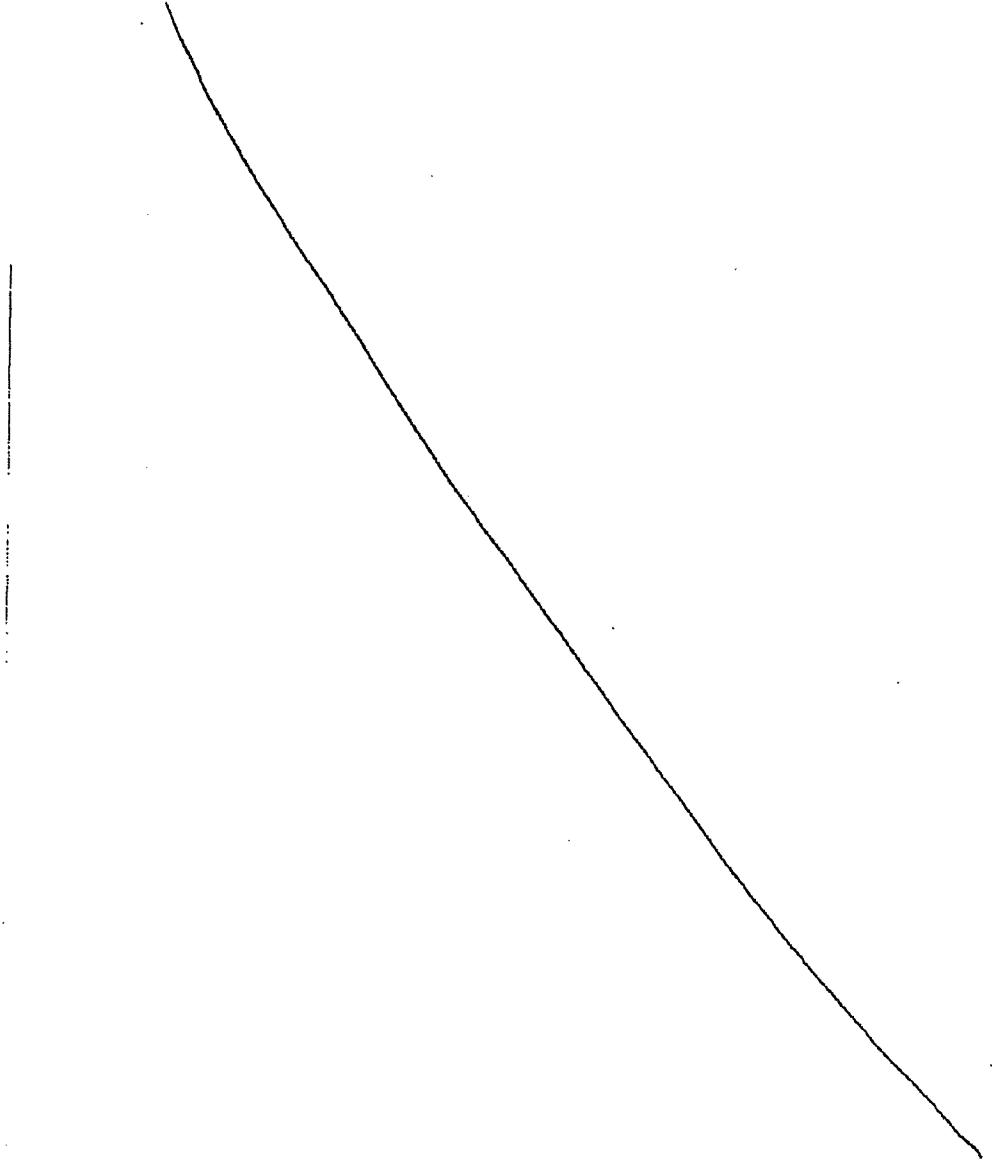
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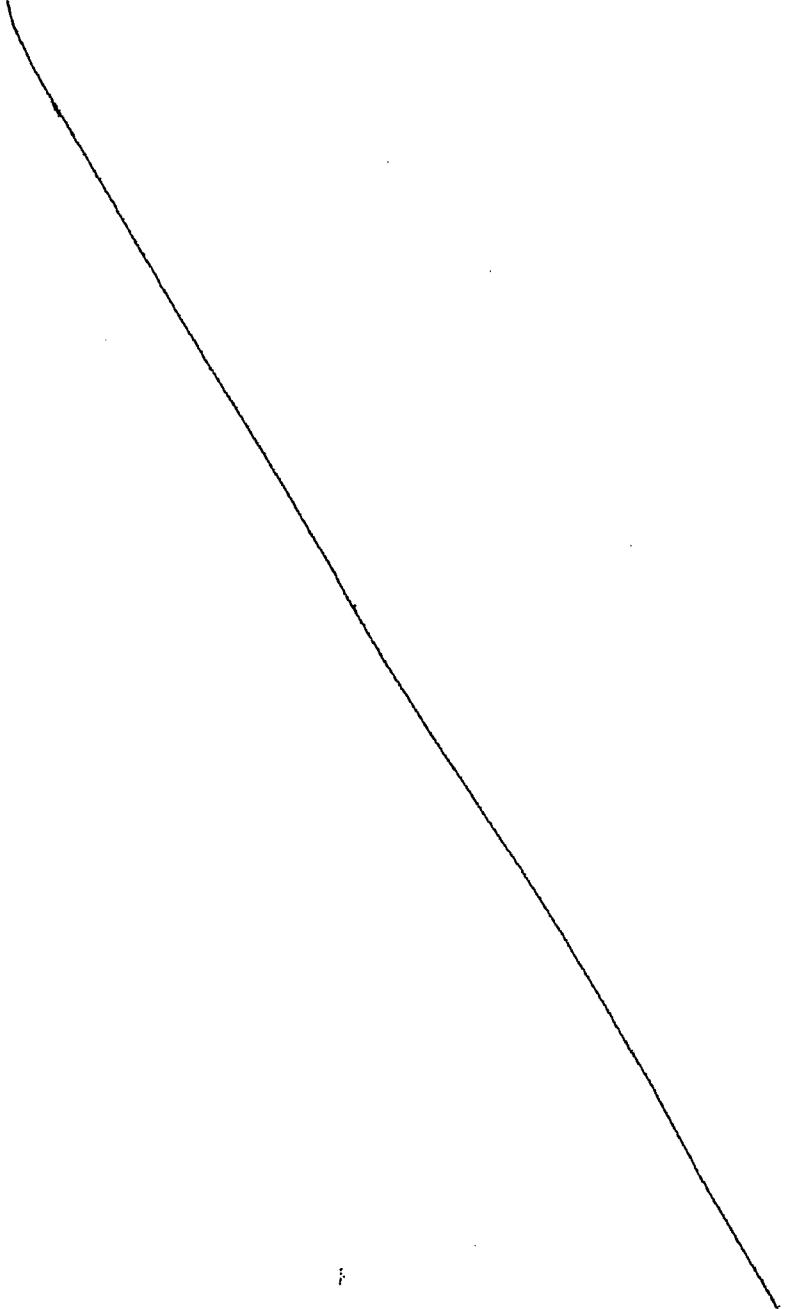
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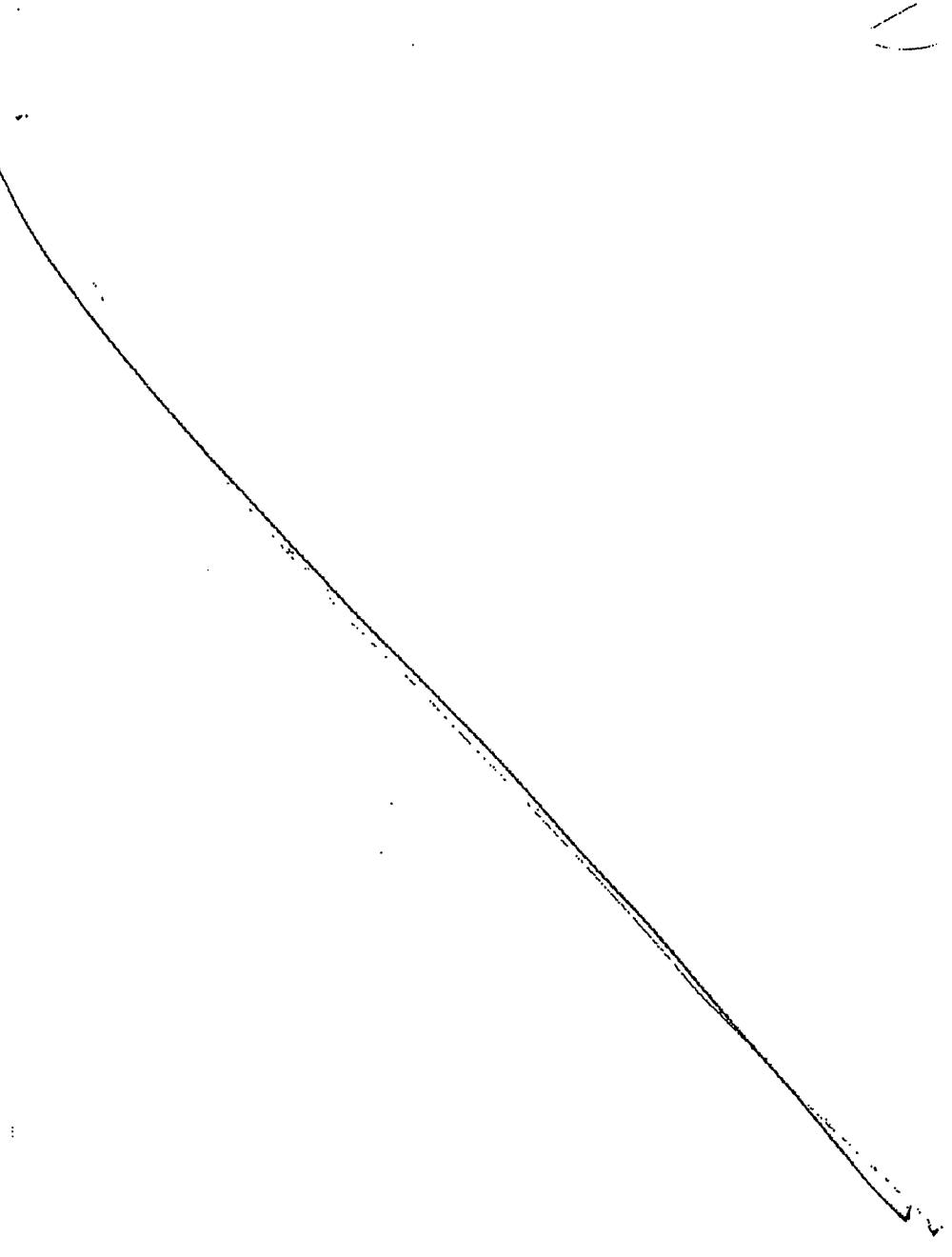


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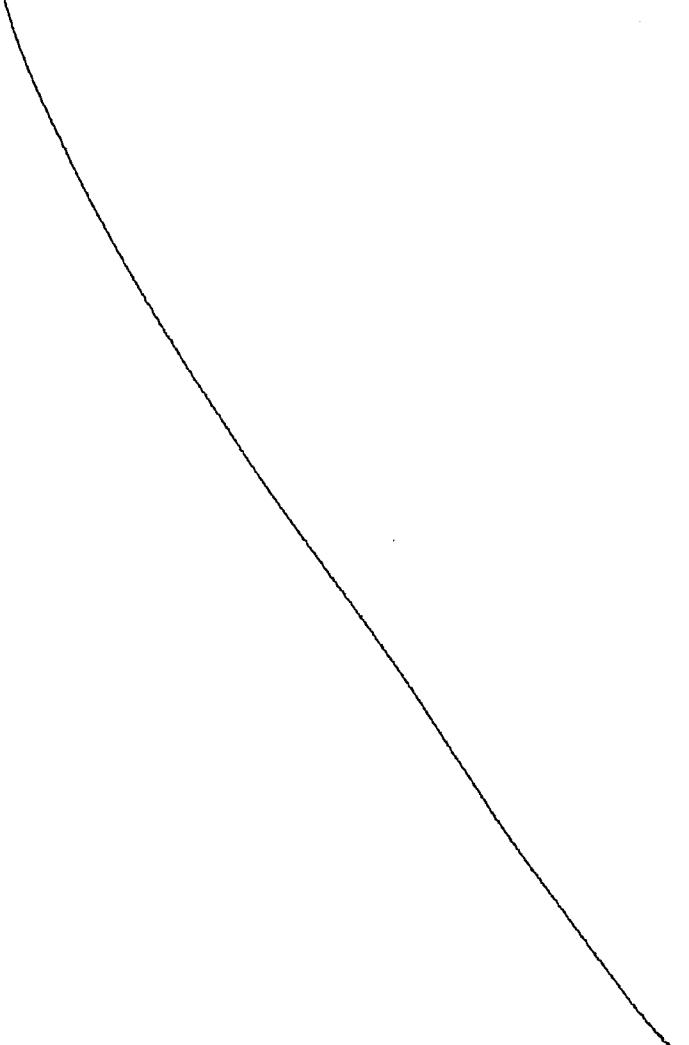
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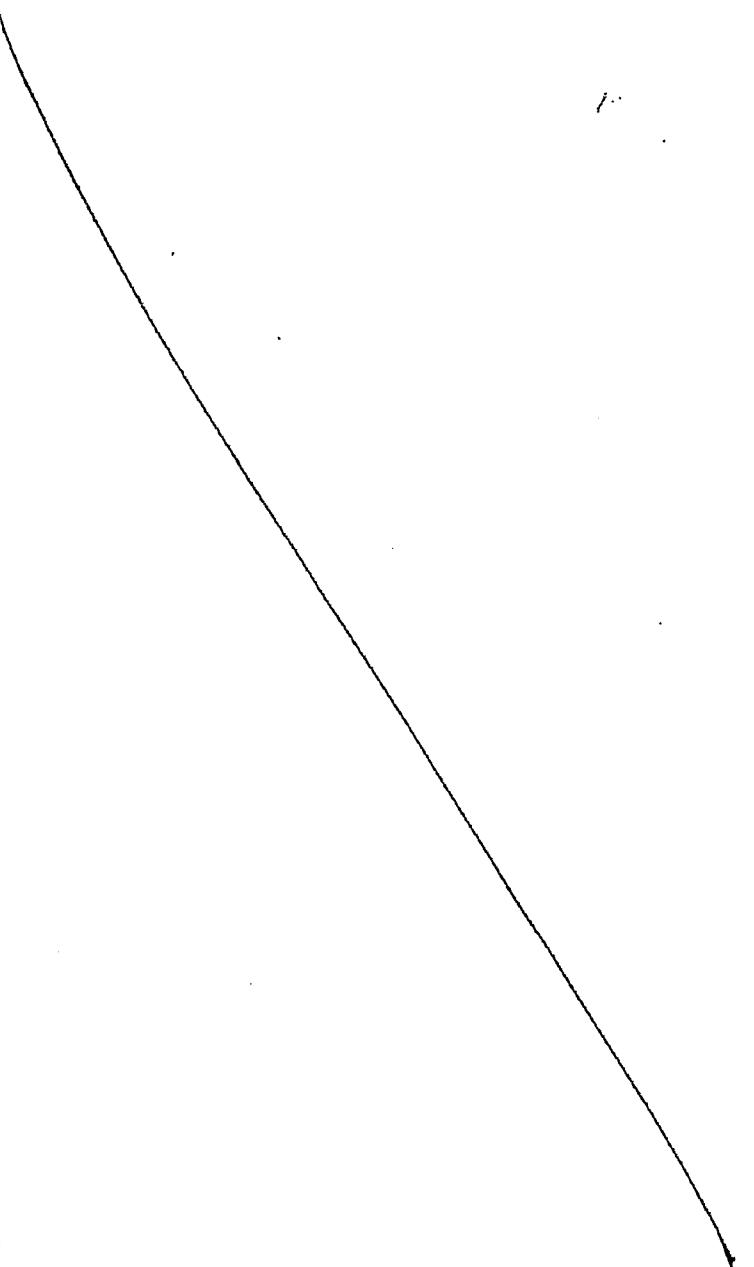
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REDACTED



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REDACTED

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Tab 5

PLAINTIFF'S
EXHIBIT
2X

ANALGESIA VENTURE

2001 PLAN

Revised 1/26/01

To:
John Leonard
Chris Silber
George Carter
Bruce McCarthy
Mike Biarnesien
Bob Funk
Mike Higgins
Mike Comilla
Matt Russell
Tom Woldat
Barbara Massa

PLAINTIFF'S
EXHIBIT
Leonard 21
1/1/2010

**Analgésia Venture
2001 PLAN Review (Pass II)
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2	ABT-594 Key Statistics
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9	NPS 1776 Key Statistics
10	NPS 1776 Grants
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12	ABS-103 Key Statistics
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15	ABT-963 Key Statistics
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19	Blue Plan Summary

**Analgesia Venture
Summary
2001 PLAN Pass II**

	2001 Target	2000 AGU	2001 PLAN	Target vs PLAN Fav/(Unfav) Yar
ABT - 594	9,300	14,411	9,307	(7) ^a
ABT - 089	...	3,000	613	(613) ^b
NPS 1776	...	"	537	(537) ^c
ABS - 103	...	"	"	" ^b
ABT - 963	...	4,000	1,186	(1,186) ^b
Venture Total	<u><u>9,300</u></u>	<u><u>21,411</u></u>	<u><u>11,643</u></u>	<u><u>(2,343)</u></u>

a Includes a \$120,000 charge from SPD not in Oracle

b Completion of work started in 2000, bringing it to a logical holding position.

c Includes a \$490,000 charge from SPD included in Oracle in error.

**Anesthesia Venture
ABT-594
2001 PLAN KEY STATISTIC
(\$000)**

<u>Project</u>	<u>2001 Target</u>	<u>2000 AGU</u>	<u>2001 PLAN</u>	<u>Target vs PLAN Fav/(Unfav) Var</u>
Neuronal nicotinic receptor antagonist (Milestone Funded to Go/No Go June, 2001)	9,300	14,411	9,307	(7)

Key Milestones / Assumptions	00 AGU		01 PLAN		Status (on target, pending or delayed to x)
	Actual	Target	Actual	Target	
- IND Filing	2/98	2/98	Completed		
- Initiate Phase II - U.S.	7/98	7/98	Completed		
- Go/No Go Clinical Efficacy (Phase IIa)	9/99	9/99	Completed		
- Go/No Go Clinical Efficacy (Phase IIb)	2/01	6/01	Delayed	Last patient enrolled 1/5/01, n = 269	
- Initiate Phase III - U.S.	9/01	4/02	Delayed		
- File NDA U.S./EMEA EU	5/03	9/03	Delayed		

PARD	08 AUG		01 PLAN
	Actual	Budget	
Analytics Dev & Support	879	641	Analytic F, Support Mitrunbu Chem & Process Justification
Formulation Dev & Support	743	226	Formulation scale-up and process optimization
Clinical Finishing	607	145	Completion of May9-11*, Pregab 3 Ph1 study supplies
Project Management Support	178	63	Coordination of activities and support of gyro 8 meeting prep
PARD Total	2,600	1,222	

SPD Requirements				
	Kay	Heads	Met Cont.	Total Cost
2000 AGU	5	1	71	306
2001 PLAN	5	...	120	120

A Increased cost result of additional CRO monitoring costs.
H.Wiembecke (Abbott) 0251-4337 handed to Paul N. Feltz - 2001 E

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Analgesia Venture
ABT-089

2001 PLAN KEY STATISTICS Page II

Project	2001			2001			Target vs PLAN Fav/(Unfav) Yr	Status (on target, pending or delayed to x)
	Target	2000 AGU	PLAN	Target	2000 AGU	PLAN		
Neuronal nicotinic receptor modulator (Unfunded)		3,000	613			(613)		
Key Milestones / Assumptions								
- Transition Team Go/No Go								
-								
-								
-								
PARD								
- Analytics Dev & Support								
- Formulation Dev & Support								
- Clinical Finishing								
- Project Management Support								
- PARD Total								
Total Venture Management								
- Expense: \$3,564 a decrease of \$3837 resulting from milestone funding (\$2,268 represents full year fixed/overhead)								
- Authorized Heads: Flat to AGU until July, 2001, ABT-594 Go/No Go Decision, no headcount after July, 2001								
Clinical Grants								
Phase I								
Total								

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**Anaesthesia Venture
NPS 1776
2001 PLAN KEY STATISTICS \$
(\$000)**

Project	2001			2000			2001			Target vs PLAN		
	Target	AGU	PLAN	Target	AGU	PLAN	Actual	Variance	Var	Actual	Variance	Var
NPS-1776 (Unfinished)	537	-	-	(537)	-	-

Key Milestones / Assumptions		Status (on target, pending or delayed to x)
DDO Meeting	00 ACU 4/2001	01 PLAN 4/2001

	<u>00 AGU</u>	<u>01 PLAN</u>
PARD		
• Analytics Dev & Support		***
• Formulation Dev & Support		***
• Clinical Finishing		***
• Project Management Support		***
PARD Total		***

Total Venture Management		SPD Requirements		R/esa	
		Kgs	Hends	Mat'l Cost	Total Cost
2000 AGU	
2001 PLAN	
					490

1st Patient	Last	R/esa
Day	CPR	2000 AGU

Clinical Grants

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2001 PLAN KEY STATISTICS **Pass**
(\$000)

PARD	W/ASU		W/PLAN	
	• Analytics Dev & Support	• Formulation Dev & Support	• Clinical Finishing	• Project Management Support
1	✓	✓	✓	✓
2	✓	✓	✓	✓
3	✓	✓	✓	✓
4	✓	✓	✓	✓
5	✓	✓	✓	✓

Total Venture Management		SPD Requirements		Cost'	
Current Grants	2001 PLAN	Kits	Heads	Matl Cost	Total Cost
• Expenses: \$3,564 a decrease of \$837 resulting from milestone funding. (\$2,268 represents full year fixed/overhead)	2000 AGU	"	"	"	"
• Authorized Heads: Flat to AGU until July, 2001, ABT-594, Go/No Go Decision, no headcount after July, 2001	2001 PLAN	"	"	"	"
		Rolls			
		2001 PLAN			

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Total
Number

Discovery ABT-963 **2001 PLAN KEY STATISTICS Page**
(5000)

PARD	01 AGU		01 PLAN	
	Actual	Variance	Actual	Variance
Analytics Dev & Support	195	-21		
Formulation Dev & Support	147	11		
Clinical Finishing	33	18		
Project Management Support	29	...		
PARD Total	404	50		

SFD Requirements	2000 AGU			2001 PLAN		
	Kgs	Heads	Mail Cont	Kgs	Heads	Mail Cont
" "	" "	" "	" "	" "	" "	" "
" "	" "	" "	" "	" "	" "	" "

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2001 PLAN vs QD AGU FAV/NURRAY		2001 PLAN										
		Patients	Start	End	Total	Enter	2000	Future	Grand Total	Plan	Actual	Grand Total
			5 Apr-01	Dec-01	185,000				185,000			
			12 Feb-01	Nov-01	100,000				100,000			
			24 Mar-01	Sep-01	500,000				500,000			
			310 Feb-00	May-01	1,000,000				1,000,000			
			410 Jul-01	Mar-02	5,261,980				5,261,980			
					(3,341,000)				(3,341,000)			
						1,715,657			1,715,657			
						(1,307,133)			(1,307,133)			
							4,065,000		4,065,000			
							(1,065,000)		(1,065,000)			

Study	ROSS	Protocol	Start	End	Total	Enter	2000	Future	Grand Total	Plan	Actual	Grand Total
Program												
Phase Ia												
Human Metabolism JH		MSP-371										
MR/Offensive pain model												
Treatment Optimization												
Phase IIb												
Neuropathic Pain (Unabetic)	107608	MSP-114	310 Apr-00	Nov-00	3,000,000							
Phase III												
BLUR PLAN												
Chronic Persistent Pain Publication												
Breakout Blue Plan Studies												
Adjustments												
Breakout Clin Trial Studies												
TOTAL												

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Anaesthesia Ventilatory
CLINICAL GRANTS
ABT-089
2001 PLAN Page 11

**Analgesia Venture
CLINICAL GRANTS
NPF 1776
2001 PLAN Fees //**

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Anesthesia Venture
CLINICAL GRANTS
ABS-103
2001 PLAN Pages 11

Discovery
CLINICAL GRANTS
ABT-963
2001 PLAN Pass II

2001 AGU PAYMENT SCHEDULE									
2001 PLAN									
Program	Study	ROSS	Period	Grand Total		Patient	Start	End	Future
				Prior	Total				
Phase I			48 Nov-00 Feb-01	261,390	130,695	130,695		261,390	
Single Rking Done EU									
Phase II									
Phase III									
Multi Rking Done			48 Mar-01 Jun-01	361,000	361,000	361,000			(361,000)
Dental Pain			260 Mar-01 Jun-01	700,000	700,000	700,000			(700,000)
Back out Blue Plan Studies					(1,061,000)	(1,061,000)			1,061,000
Adjustments:									" "
Back out Clin Pharm Studies									" "
TOTAL						261,390	130,695	130,695	261,390
									261,390

Amgenia Ventures
2001 PLAN
\$4,600

Actual	EXPENSE	2000	AGU	2001 PLAN		
				Merit/Fringe:	Head Count	% Inv.(Unitary)
1,172.6	Net Payroll	1,099.4	(41.3)	"	"	103.8%
99.7	Solentillo Professionals	98.1	(4.0)	(0.8)	"	102.9
124.8	Travel and Entertainment	132.7	"	"	125.3	104.5%
52.7	Other Employee Related	54.4	"	"	29.8	27.4
0.1	Clinical Supplies	"	"	"	"	24.6
18.2	Care Report Forms	17.1	"	"	6.2	45.2%
222.5	Consultantship/Honorariums	160.5	"	"	97.8	62.7
"	HBD Project Charges	"	"	(4,028.0)	4,028.0	HBD冲销(或增加)
462.5	Other Operating	461.5	"	"	338.5	123.0
203.7	Fixed Expenses	203.7	"	"	(26.3)	210.0
2,351.8	Total Functional Expenses	2,347.4	(45.3)	(0.8)	(3,454.7)	5,748.2
2,154.0	Overhead	2,154.0	"	"	(114.0)	2,268.0
4,511.8	Gross Expense	4,401.4	(45.3)	(0.9)	(3,568.7)	8,066.2

Actual	HEADCOUNT	YE Authorized		
		2000	2001 AGO	2001 PLAN
6	EXEMPT	7	6	6
5	NON-EXEMPT	6	5	5
11	TOTAL REGULAR	13	11	11
2	SCIENTIFIC PROFESSIONALS	1	2	2
1	CONTRACTS	"	1	1
14	TERMS	"	"	"
14	Sub Total	14	14	14
14	UNFILLED	2	4	4
14	Total Authorized Headcount	16	18	18

* Payroll/Fringe for the full year, assuming Neuroptix Pan is funded
** Payroll/Fringe for the full year, for current Amgen Employees

214-6-02

04/11 PM

curr	661,318.0
gross	7,226.6
total pay	670,544.6
fringe	236,039.9
total fringe	906,584.4
curr bonus ex	144,556.0
promo	1,443.6
total pay	145,000.6
fringe	56,392.6
total fringe	202,394.2

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*Analgésia Centralizada Headcount
2001 PLAN Pass II*

Budgeted	Dec	Nov	Oct	Sep	Aug	Jul	Jun	May	Apr	Mar	Feb	Jan	Title	Name
----------	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	-------	------

Sci/Pro	Borgström	Marian	Sci/Pro
Sci/Pro	Davis	Jan	Sci/Pro
Sci/Pro	Christensen	Pivllys	Sci/Pro
Sci/Pro	Blare-Michaels	Molly	Sci/Pro

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**Analgesia Centralized Headcount
2001 PLAN Pass II**

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Blue Plan Summaries

ABT 594 ABT 594 ABT 089 ABS 103 NPS 1776 ABT 963
Milestone CPPP
BP 143010 BP 143014 BP 143100 BP 121200 BP 121100 BP 414030

Payroll	698					
Other Functionals	376					
Grants						
Investigational Drug Discovery	51	5,261	1,628	525	1,817	1,061
Drug Safety	853	701	859	949	154	
PARD	2,815		2,172	1,600	1,335	1,837
Phase I Center	43	22	1,042	840	1,840	1,029
Development Ops	235	271	157	193	254	629
RA/QA	22	22	340	123	335	590
Medical Affairs			17	19	69	65
Admin			55	33	39	138
SPD	970		70			
Milestone Payment				1,000		
Total						
	6,063	6,277	6,340	5,282	5,843	5,249

A B C D D F

- A Neuropathic Pain Study completion and gear up for Phase III to support current filing target.
- B Maximize spill over in Neuropathic pain use.
- C Transition funding to achieve first go/no go milestone. Determine formulation feasibility and tox work for both adults and children.
- D Initiation of Phase I studies
- E End of Phase I milestone, safety PK and formulation requirements
- F Phase I multi does and 3 month safety studies in two species.